UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,771,352 C1
APPLICATION NO. : 90/011468
DATED : October 4, 2011
INVENTOR(S) : Shults et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Issued Patent Column	Issued Patent Line	Description of Discrepancy
1	57 (Approx.)	In Claim 15, after “33,” insert --wherein the--.
1	60	In Claim 16, change “33” to --33,--.
1	62	In Claim 16, change “0.00003 in ^{2}to” to --0.00002 in^2 to--.
2	15 (Approx.)	In Claim 30, change “0.00079 in ^{2}.” to --0.0079 in^2.--.

Signed and Sealed this
Seventeenth Day of April, 2012

David J. Kappos

David J. Kappos
Director of the United States Patent and Trademark Office

Knobbe Martens Olson & Bear LLP

Intellectual Property Law

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Rose M. Thiessen, Ph.D.

March 12, 2012

ATTN: Certificate of Correction Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: Title: LOW OXYGEN IN VIVO ANALYTE SENSOR
Letters Patent No. 7771352 C1
Issued: October 4, 2011
Our Reference: DEXCOM.63C2X

Dear Sir:

Enclosed for filing is a Certificate of Correction in connection with the above-identified patent.

As the errors cited in the Certificate of Correction were incurred through the fault of the Patent Office, no fee is believed to be required. However, please charge our Deposit Account No. 11-1410 for any fees that may be incurred with this request.

Respectfully submitted,

Knobbe, Martens, Olson & Bear, LLP

Rose M. Thiessen
Registration No. 40,202
Customer No. 68851

Enclosures

12916875:JSJ
031212

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7771352 C1

APPLICATION NO. : 90/011468

ISSUE DATE : October 4, 2011

INVENTOR(S) : Shults, et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

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2	15 (Approx.)	In Claim 30, change "0.00079 in ^{2}." to --0.0079 in^2.--.

12916863
031212

MAILING ADDRESS OF SENDER:

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2040 Main Street, 14th Floor
Irvine, California 92614

DOCKET NO. DEXCOM.63C2X

PTO/SB/44 Equivalent

US007771352C1

(12) **EX PARTE REEXAMINATION CERTIFICATE** (8611th)

United States Patent

Shults et al.

(10) **Number: US 7,771,352 C1**

(45) **Certificate Issued: Oct. 4, 2011**

(54) **LOW OXYGEN IN VIVO ANALYTE SENSOR**

(75) Inventors: **Mark C. Shults**, Madison, WI (US); **Rathburn K. Rhodes**, Madison, WI (US); **Stuart J. Updike**, Madison, WI (US); **James H. Brauker**, Cement City, MI (US)

(73) Assignee: **DexCom, Inc.**, San Diego, CA (US)

Reexamination Request:
No. 90/011,468, Feb. 1, 2011

Reexamination Certificate for:

Patent No.:	**7,771,352**
Issued:	**Aug. 10, 2010**
Appl. No.:	**12/113,508**
Filed:	**May 1, 2008**

Certificate of Correction issued Feb. 15, 2011.

Related U.S. Application Data

(63) Continuation of application No. 11/333,837, filed on Jan. 17, 2006, now Pat. No. 7,899,511, which is a continuation-in-part of application No. 11/077,714, filed on Mar. 10, 2005, now Pat. No. 7,885,697.

(60) Provisional application No. 60/614,683, filed on Sep. 30, 2004, provisional application No. 60/614,764, filed on Sep. 30, 2004, provisional application No. 60/587,787, filed on Jul. 13, 2004, and provisional application No. 60/587,800, filed on Jul. 13, 2004.

(51) **Int. Cl.**

A61B 5/00	(2006.01)
A61B 5/05	(2006.01)

(52) **U.S. Cl.** **600/365**; 600/347

(58) **Field of Classification Search** .... None
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,893,552	B1	5/2005	Wang et al.
7,899,511	B2	3/2011	Shults et al.
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2003/0032874	A1	2/2003	Rhodes et al.
2004/0173472	A1	9/2004	Jung et al.
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FOREIGN PATENT DOCUMENTS

WO	WO 01/20019	3/2001

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EPO Communication [DEXCOM: 063VEP] dated Feb. 26, 2010 in Application No. EP 06718980.3, filed Jan. 17, 2006.

Kerner. et al., A Potentially Implantable Enzyme Electrode for Amperometric Measurement of Glucose, Horm Metab Res Suppl., 20:8–13 (1989).

Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissolved oxygen, Clin. Phys. Physiol. Meas., vol. 10, 1:1–19 (1989).

Sternberg, et al., Covalent Enzyme Coupling on Cellulose Acetate Membranes for Glucose Sensor Development, Anal. Chem., 60:2781–2786 (1988).

Primary Examiner—Beverly M. Flanagan

(57) **ABSTRACT**

The present invention relates generally to systems and methods for measuring an analyte in a host. More particularly, the present invention relates to systems and methods for transcutaneous and subcutaneous measurement of glucose in a host.

EX PARTE REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claims **7**, **8**, **10**, **11**, **13**, **17**, **19**, **20**, **22**, **24-26** and **28** is confirmed.

Claims **1**, **14** and **23** are cancelled.

Claims **2-6**, **9**, **12**, **15**, **16**, **18**, **21**, **27** and **29-31** are determined to be patentable as amended.

New claims **32-37** are added and determined to be patentable.

2. The continuous glucose sensor system of claim **[1]** *32*, wherein the system is configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation.

3. The continuous glucose sensor system of claim **[1]** *32*, wherein the oxygen concentration is less than about 0.15 mg/L.

4. The continuous glucose sensor system of claim **[1]** *32*, wherein the oxygen concentration is less than about 0.05 mg/L.

5. The continuous glucose sensor system of claim **[1]** *32*, wherein the oxygen concentration is less than about 0.02 mg/L.

6. The continuous glucose sensor system of claim **[1]** *32*, wherein the electrode comprises an exposed electroactive working electrode surface with a surface area of from about 0.00002 in^2 to about 0.0079 in^2.

9. The continuous glucose sensor system of claim **[1]** *32*, wherein the sensor system is configured to have, in operation, a sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL.

12. The continuous glucose sensor system of claim **[1]** *32*, wherein the resistance domain comprises a polyurethane.

15. The continuous glucose sensor system of claim **[14]** *33*, oxygen concentration is less than about 0.3 mg/L.

16. The continuous glucose sensor system of claim **[14]** *33* wherein the electrode comprises an exposed electroactive working electrode surface with a surface area of from about 0.00003 in ^{2}to about 0.0079 in^2.

18. The continuous glucose sensor system of claim **[14]** *33*, wherein the sensor system is configured to have, in operation, a sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL.

21. The continuous glucose sensor system of claim **[14]** *33*, wherein the resistance domain comprises a polyurethane.

27. The continuous glucose sensor system of claim **[23]** *34*, wherein the resistance domain comprises a polyurethane.

29. The continuous glucose sensor system of claim **[23]** *34*, wherein the oxygen concentration is less than about 0.3 mg/L.

30. The continuous glucose sensor system of claim **[23]** *34*, wherein the electrode comprises an exposed electroactive working electrode surface with a surface area of from about 0.00002 in^2 to about 0.00079 in ^{2}.

31. The continuous glucose sensor system of claim **[23]** *34*, wherein the resistance domain is configured to have a permeability ratio of at least about 50:1 of oxygen to glucose.

32. A continuous glucose sensor system comprising:

an implantable body comprising an electrode configured to measure a glucose level in a host;

a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme configured to catalyze a reaction of glucose and oxygen from a biological fluid surrounding the membrane; and

sensor electronics operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in the biological fluid with an oxygen concentration of less than about 0.3 mg/L.

33. A continuous glucose sensor system comprising:

an implantable body comprising an electrode configured to measure a glucose level in a host;

a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme configured to catalyze a reaction of glucose and oxygen from a biological fluid surrounding the membrane; and

a sensor electronics unit operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a biological fluid with an oxygen concentration of less than about 0.6 mg/L, wherein the system is configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation.

34. A continuous glucose sensor system comprising:

an implantable body comprising an electrode configured to measure a glucose level in a host;

a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme configured to catalyze a reaction of glucose and oxygen; and

a sensor electronics unit operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in the biological

fluid with an oxygen concentration of less than about 0.45 mg/L, wherein the sensor system is configured to have, in operation, a sensitivity of from about 5 pA/mg/dL to about 25 pA/mg/dL.

35. The continuous glucose sensor system of claim 34, wherein the biological fluid has an oxygen concentration of less than about 0.4 mg/L.

36. The continuous glucose sensor system of claim 34, wherein the biological fluid has an oxygen concentration of less than about 0.35 mg/L.

37. The continuous glucose sensor system of claim 34, wherein the biological fluid has an oxygen concentration of less than about 0.3 mg/L.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/011,468	02/01/2011	771352	DEXCOM.63C2X	9182

20995 7590 08/29/2011

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	

ART UNIT	PAPER NUMBER

DATE MAILED: 08/29/2011

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
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AUG 29 2011

CENTRAL REEXAMINATION UNIT

(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

Abbott Diabetes Care, Inc.
Bozicevic, Field & Francis, LLP
1900 University Avenue, Suite 200
East Palo Alto, CA 94303

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. 90/011,468.

PATENT NO. 771352.

ART UNIT 3993.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Notice of Intent to Issue Ex Parte Reexamination Certificate	Control No.	Patent Under Reexamination	
	90/011,468	7771352	
	Examiner	Art Unit	
	BEVERLY FLANAGAN	3993	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

1. ☒ Prosecution on the merits is (or remains) closed in this *ex parte* reexamination proceeding. This proceeding is subject to reopening at the initiative of the Office or upon petition. *Cf.* 37 CFR 1.313(a). A Certificate will be issued in view of
   (a) ☒ Patent owner's communication(s) filed: *28 June 2011*.
   (b) ☐ Patent owner's late response filed: _____.
   (c) ☐ Patent owner's failure to file an appropriate response to the Office action mailed: _____.
   (d) ☐ Patent owner's failure to timely file an Appeal Brief (37 CFR 41.31).
   (e) ☐ Other: _____.

   Status of *Ex Parte* Reexamination:
   (f) Change in the Specification: ☐ Yes ☒ No
   (g) Change in the Drawing(s): ☐ Yes ☒ No
   (h) Status of the Claim(s):
      (1) Patent claim(s) confirmed: *7,8,10,11,13,17,19,20,22,24-26 and 28*.
      (2) Patent claim(s) amended (including dependent on amended claim(s)): *2-6,9,12,15,16 and 18*
      (3) Patent claim(s) canceled: *1,14 and 23*.
      (4) Newly presented claim(s) patentable: 32-37.
      (5) Newly presented canceled claims: _____.
      (6) Patent claim(s) ☐ previously ☐ currently disclaimed: _____
      (7) Patent claim(s) not subject to reexamination: _____.

2. ☒ Note the attached statement of reasons for patentability and/or confirmation. Any comments considered necessary by patent owner regarding reasons for patentability and/or confirmation must be submitted promptly to avoid processing delays. Such submission(s) should be labeled: "Comments On Statement of Reasons for Patentability and/or Confirmation."
3. ☐ Note attached NOTICE OF REFERENCES CITED (PTO-892).
4. ☐ Note attached LIST OF REFERENCES CITED (PTO/SB/08 or PTO/SB/08 substitute).
5. ☐ The drawing correction request filed on _____ is: ☐ approved ☐ disapproved.
6. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
   a)☐ All b)☐ Some* c)☐ None of the certified copies have
   ☐ been received.
   ☐ not been received.
   ☐ been filed in Application No. _____.
   ☐ been filed in reexamination Control No. _____.
   ☐ been received by the International Bureau in PCT Application No. _____.

   * Certified copies not received: _____.
7. ☐ Note attached Examiner's Amendment.
8. ☒ Note attached Interview Summary (PTO-474).
9. ☐ Other: _____.

cc: Requester (if third party requester)

Claims Patentable and Confirmed

Claims 7, 8, 10, 11, 13, 17, 19, 20, 22, 24-26 and 28 are confirmed. Claims 2-6, 9, 12, 15, 16, 18, 21, 27 and 29-31 are patentable as amended. Newly filed claims 32-37 are patentable. Claims 1, 14 and 23 are canceled.

STATEMENT OF REASONS FOR PATENTABILITY AND/OR CONFIRMATION

The following is an examiner's statement of reasons for patentability and/or confirmation of the claims found patentable in this reexamination proceeding: The prior art does not teach or fairly address the invention as recited in claims 2-13, 15-22 and 24-37 of U.S. Patent No. 7,711,352. Specifically, the examiner agrees with patent owner that the applied prior art reference Kusano is not configured to use oxygen from surrounding biological fluid, but instead uses oxygen from ambient air. Additionally, the examiner agrees with patent owner that there is no motivation to combine the teachings of Kusano and Sternberg or Kusano and Rhodes because it would render the Kusano device unsuitable for its intended purpose. The examiner also agrees that the applied prior art reference of Rhodes does not teach a sensor capable of achieving substantial linearity at glucose concentrations of up to about 400 mg/dL. Claims 2-13, 15-22 and 24-37 are thus patentable.

Any comments considered necessary by PATENT OWNER regarding the above statement must be submitted promptly to avoid processing delays. Such submission by the patent owner should be labeled: "Comments on Statement of Reasons for Patentability and/or Confirmation" and will be placed in the reexamination file.

Conclusion

Please mail any communications to:

Attn: Mail Stop "Ex Parte Reexam"
Central Reexamination Unit
Commissioner for Patents
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Alexandria, VA 22313-1450

Please FAX any communications to:

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Central Reexamination Unit

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Attn: Central Reexamination Unit
Randolph Building, Lobby Level
401 Dulaney Street
Alexandria, VA 22314

Any inquiry concerning this communication or earlier communications from the Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:

/Beverly M. Flanagan/

Beverly M. Flanagan
CRU Examiner
GAU 3993
(571) 272-4766

Conferee /JRJ/

Conferee ________

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	US 7,711,352
App. No	:	90/011,468
Filed	:	2/01/2011
For	:	LOW OXYGEN IN VIVO ANALYTE SENSOR
Examiner	:	Flanagan, Beverly M.
Art Unit	:	3993
Conf No.	:	9182

AMENDMENT

Mail Stop *Ex Parte* Reexam
Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action dated April 28, 2011, for which a response is due on June 28, 2011, Patent Owner herewith submits a response and respectfully requests reconsideration and allowance of the pending claims in light of the remarks presented herein.

Amendment to the Claims begins on page 2 of this paper.

Summary of Interview begins on page 6 of this paper.

Claim Status and Support for Amendments begins on page 7 of this paper.

Remarks begin on page 10 of this paper.

AMENDMENT TO THE CLAIMS

1. (Canceled)

2. (Currently Amended) The continuous glucose sensor system of Claim 32 [1], wherein the system is configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation.

3. (Currently Amended) The continuous glucose sensor system of Claim 32 [1], wherein the oxygen concentration is less than about 0.15 mg/L.

4. (Currently Amended) The continuous glucose sensor system of Claim 32 [1], wherein the oxygen concentration is less than about 0.05 mg/L.

5. (Currently Amended) The continuous glucose sensor system of Claim 32 [1], wherein the oxygen concentration is less than about 0.02 mg/L.

6. (Currently Amended) The continuous glucose sensor system of Claim 32 [1], wherein the electrode comprises an exposed electroactive working electrode surface with a surface area of from about 0.00002 in^2 to about 0.0079 in^2.

7. (Original) The continuous glucose sensor system of Claim 1, wherein the resistance domain is configured to have a permeability ratio of at least about 50:1 of oxygen to glucose.

8. (Original) The continuous glucose sensor system of Claim 7, wherein the resistance domain is configured to have a permeability ratio of at least about 200:1 of oxygen to glucose.

9. (Currently Amended) The continuous glucose sensor system of Claim 32 [1], wherein the sensor system is configured to have, in operation, a sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL.

10. (Original) The continuous glucose sensor system of Claim 1, wherein the resistance domain comprises a silicone.

11. (Original) The continuous glucose sensor system of Claim 1, wherein the resistance domain comprises a fluorocarbon.

12. (Currently Amended) The continuous glucose sensor system of Claim 32 [1], wherein the resistance domain comprises a polyurethane.

13. (Original) The continuous glucose sensor system of Claim 1, wherein the resistance domain comprises a polyethylene oxide.

14. (Canceled)

15. (Currently Amended) The continuous glucose sensor system of Claim 33 [14], wherein the oxygen concentration is less than about 0.3 mg/L.

16. (Currently Amended) The continuous glucose sensor system of Claim 33 [14], wherein the electrode comprises an exposed electroactive working electrode surface with a surface area of from about 0.00002 in^2 to about 0.0079 in^2.

17. (Original) The continuous glucose sensor system of Claim 14, wherein the resistance domain is configured to have a permeability ratio of at least about 50:1 of oxygen to glucose.

18. (Currently Amended) The continuous glucose sensor system of Claim 33 [14], wherein the sensor system is configured to have, in operation, a sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL.

19. (Original) The continuous glucose sensor system of Claim 14, wherein the resistance domain comprises a silicone.

20. (Original) The continuous glucose sensor system of Claim 14, wherein the resistance domain comprises a fluorocarbon.

21. (Currently Amended) The continuous glucose sensor system of Claim 33 [14], wherein the resistance domain comprises a polyurethane.

22. (Original) The continuous glucose sensor system of Claim 14, wherein the resistance domain comprises a polyethylene oxide.

23. (Canceled)

24. (Original) The continuous glucose sensor system of Claim 23, wherein the system is configured such that less than about 1 μg of enzyme is consumed over 10 days of continuous operation.

25. (Original) The continuous glucose sensor system of Claim 23, wherein the resistance domain comprises a silicone.

26. (Original) The continuous glucose sensor system of Claim 23, wherein the resistance domain comprises a fluorocarbon.

27. (Currently Amended) The continuous glucose sensor system of Claim 34 [23], wherein the resistance domain comprises a polyurethane.

28. (Original) The continuous glucose sensor system of Claim 23, wherein the resistance domain comprises a polyethylene oxide.

29. (Currently Amended) The continuous glucose sensor system of Claim <u>34</u> [23], wherein the oxygen concentration is less than about 0.3 mg/L.

30. (Currently Amended) The continuous glucose sensor system of Claim <u>34</u> [23], wherein the electrode comprises an exposed electroactive working electrode surface with a surface area of from about 0.00002 in^2 to about 0.0079 in^2.

31. (Currently Amended) The continuous glucose sensor system of Claim <u>34</u> [23], wherein the resistance domain is configured to have a permeability ratio of at least about 50:1 of oxygen to glucose.

<u>32. (New) A continuous glucose sensor system comprising:</u>

<u>an implantable body comprising an electrode configured to measure a glucose level in a host;</u>

<u>a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme configured to catalyze a reaction of glucose and oxygen from a biological fluid surrounding the membrane; and</u>

<u>sensor electronics operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in the biological fluid with an oxygen concentration of less than about 0.3 mg/L.</u>

<u>33. (New) A continuous glucose sensor system comprising:</u>

<u>an implantable body comprising an electrode configured to measure a glucose level in a host;</u>

<u>a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme configured to catalyze a reaction of glucose and oxygen from a biological fluid surrounding the membrane; and</u>

<u>a sensor electronics unit operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a biological fluid with an oxygen</u>

concentration of less than about 0.6 mg/L, wherein the system is configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation.

34. (New) A continuous glucose sensor system comprising:

an implantable body comprising an electrode configured to measure a glucose level in a host;

a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme configured to catalyze a reaction of glucose and oxygen; and

a sensor electronics unit operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in the biological fluid with an oxygen concentration of less than about 0.45 mg/L, wherein the sensor system is configured to have, in operation, a sensitivity of from about 5 pA/mg/dL to about 25 pA/mg/dL.

35. (New) The continuous glucose sensor system of Claim 34, wherein the biological fluid has an oxygen concentration of less than about 0.4 mg/L.

36. (New) The continuous glucose sensor system of Claim 34, wherein the biological fluid has an oxygen concentration of less than about 0.35 mg/L.

37. (New) The continuous glucose sensor system of Claim 34, wherein the biological fluid has an oxygen concentration of less than about 0.3 mg/L.

SUMMARY OF INTERVIEW

Attendees, Date and Type of Interview

The personal interview was conducted on May 19, 2011 and attended by Examiners Beverly Flangan, David Reip, and Andy Kashnikow, and Patent Owner's representatives Laura Johnson, Kaare Larson, and Paul Lee (via telephone).

Exhibits and/or Demonstrations

N/A.

Identification of Claims Discussed

Claims 1, 14, and 23 of U.S. Patent No. 7,771,352 ("the '352 Patent").

Identification of Art Discussed

Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissolved oxygen, *Clin. Phys. Physiol. Meas.*, vol. 10, 1:1-9 (1989) ("Kusano") and U.S. Patent Publication No. 2003/0032874 ("Rhodes").

Proposed Amendments, Principal Arguments, Results of Interview, and Other Matters

Patent Owner's representatives proposed amending certain claims to clarify that the oxygen used by the continuous glucose sensor system was not directly supplied from ambient air. Patent Owner's representatives explained that the combination suggested in the Office Action of combining the teachings of Kusano and Rhodes would not have been obvious and would likely have led to unpredictable results. The Examiners agreed to consider the arguments in a formal response.

CLAIM STATUS AND SUPPORT FOR AMENDMENTS (37 CFR 1.530(e))

1. **Canceled.**
2. **Pending – Amended.** Claim 2 has been amended to depend from new Claim 32.
3. **Pending – Amended.** Claim 3 has been amended to depend from new Claim 32.
4. **Pending – Amended.** Claim 4 has been amended to depend from new Claim 32.
5. **Pending – Amended.** Claim 5 has been amended to depend from new Claim 32.
6. **Pending – Amended.** Claim 6 has been amended to depend from new Claim 32.
7. **Pending – Unchanged.**
8. **Pending – Unchanged.**
9. **Pending – Amended.** Claim 9 has been amended to depend from new Claim 32.
10. **Pending – Unchanged.**
11. **Pending – Unchanged.**
12. **Pending – Amended.** Claim 12 has been amended to depend from new Claim 32.
13. **Pending – Unchanged.**
14. **Canceled.**
15. **Pending – Amended.** Claim 15 has been amended to depend from new Claim 33.
16. **Pending – Amended.** Claim 16 has been amended to depend from new Claim 33.
17. **Pending – Unchanged.**
18. **Pending – Amended.** Claim 18 has been amended to depend from new Claim 33.
19. **Pending – Unchanged.**
20. **Pending – Unchanged.**
21. **Pending – Amended.** Claim 21 has been amended to depend from new Claim 33.
22. **Pending – Unchanged.**
23. **Canceled.**
24. **Pending – Unchanged.**
25. **Pending – Unchanged.**
26. **Pending – Unchanged.**
27. **Pending – Amended.** Claim 27 has been amended to depend from new Claim 34.
28. **Pending – Unchanged.**
29. **Pending – Amended.** Claim 29 has been amended to depend from new Claim 34.

30. **Pending – Amended.** Claim 30 has been amended to depend from new Claim 34.

31. **Pending – Amended.** Claim 31 has been amended to depend from new Claim 34.

32. **Pending – New.** New Claim 32 includes all limitations of previous Claim 1 and also includes the limitation that "oxygen [is] from a biological fluid surrounding the membrane." Support for this limitation can be found, *e.g.*, at Col. 7, Lns. 39-46 and Col. 75, Ln. 63 – Col. 76, Ln. 2 of the '352 Patent.

33. **Pending – New.** New Claim 33 includes all limitations of previous Claim 14 and also includes the limitation that "oxygen [is] from a biological fluid surrounding the membrane." Support for this limitation can be found, *e.g.*, at Col. 7, Lns. 39-46 and Col. 75, Ln. 63 – Col. 76, Ln. 2 of the '352 Patent.

34. **Pending – New.** New Claim 34 includes all limitations of previous Claim 23, except the limitation of "substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L," which has been replaced with "substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.45 mg/L." Support for these limitations can be found, *e.g.*, at original Claim 23 and FIG. 29 of the '352 Patent.

35. **Pending – New.** New Claim 35 includes the limitation that "the biological fluid has an oxygen concentration of less than about 0.4 mg/L." Support for this limitation can be found, *e.g.*, in FIG. 29 of the '352 Patent.

36. **Pending – New.** New Claim 36 includes the limitation that "the biological fluid has an oxygen concentration of less than about 0.35 mg/L." Support for this limitation can be found, *e.g.*, in FIG. 29 of the '352 Patent.

37. **Pending – New.** New Claim 37 includes the limitation that "the biological fluid has an oxygen concentration of less than about 0.3 mg/L." Support for this limitation can be found, *e.g.*, in FIG. 29 of the '352 Patent.

REMARKS

Claim Status

Claims 1-9, 12, 14-18, 21, 23, 24, 27, and 29-31 of U.S. Patent No. 7,771,352 ("the '352 Patent") are under reexamination. By virtue of this Amendment, Claims 2-6, 9, 12, 15-18, 21, 24, 27, and 29-31 have been amended, Claims 1, 14, and 23 have been canceled, and new Claims 32-37 have been added. Accordingly, upon entry of this Amendment, Claims 2-9, 12, 15-18, 21, 24, 27, and 29-37 will be under reexamination.

Prior Art Rejections

A. Claims 1, 3-6, 9, and 12 are patentable over Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissolved oxygen, *Clin. Phys. Physiol. Meas.*, vol. 10, 1:1-9 (1989) ("Kusano").

Claims 1, 3-6, 9, and 12 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by Kusano. The Patent Owner respectfully traverses this anticipatory rejection. "A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." *See, e.g., In re Paulsen*, 31 U.S.P.Q.2d 1671 (Fed. Cir. 1994).

Claim 1, from which Claims 3-6, 9, and 12 previously depended, has been canceled and replaced with Claim 32. Claims 3-6, 9, and 12 have been amended to now depend from Claim 32. Claim 32 includes all limitations of previous Claim 1 and includes the limitation that the oxygen used to catalyze a reaction of glucose and oxygen is "from a biological fluid surrounding the membrane." Support for this limitation can be found, *e.g.*, at Col. 7, Lns. 39-46 and Col. 75, Ln. 63 – Col. 76, Ln. 2 of the '352 Patent.

The Patent Owner respectfully submits that Kusano fails to disclose a system configured such that the oxygen used to catalyze a reaction of glucose and oxygen is from a biological fluid surrounding the membrane. Instead, Kusano teaches a device in which oxygen is supplied to its system via an air intake from ambient air, where oxygen exists at a much higher level than that in biological fluid. In fact, Kusano expressly states that "[t]he design of [its] electrodes exposes the upper part, allowing **oxygen to be utilised** as mediator **from the ambient air <u>rather than</u> from that dissolved in the interstitial fluid**." [Bolding and underlining added for emphasis.] Kusano,

at page 2. From this description, it would be readily apparent to those of ordinary skill in the art that the Kusano device is not configured to use oxygen from surrounding biological fluid. For at least the reason that Kusano does not teach a system configured such that the oxygen used to catalyze a reaction of glucose and oxygen is from a biological fluid surrounding the membrane, the Patent Owner submits that new Claim 32 is distinguished from Kusano and that the anticipatory rejection of Claims 3-6, 9, and 12 cannot stand. Accordingly, withdrawal of this anticipatory rejection is respectfully requested.

B. Claims 2, 14-16, 18, and 21 are patentable over Kusano in view of Sternberg, *et al.*, Covalent Enzyme Coupling on Cellulose Acetate Membranes for Glucose Sensor Development, *Analytical Chemistry*, 60: 2781-2786 (1988) ("Sternberg")

Claims 2, 14-16, 18, and 21 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Kusano in view of Sternberg. The Patent Owner respectfully traverses this obviousness rejection.

It is well settled that the Examiner "bears the initial burden of presenting a *prima facie* case of unpatentability..." *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007). Until the Examiner has established a *prima facie* case of obviousness, Applicants need not present arguments or evidence of non-obviousness. To establish a *prima facie* case of obviousness, the Examiner must establish at least three elements. First, the prior art reference (or references when combined) must teach or suggest all of the claim limitations: "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 165 U.S.P.Q. 494, 496 (CCPA 1970); *see also M.P.E.P. § 2143.03*. Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091 (Fed. Cir. 1986); *see also M.P.E.P. § 2143.02*. And finally, the Examiner must articulate some reason to modify or combine the cited references that renders the claim obvious. Merely establishing that the claimed elements can be found in the prior art is not sufficient to establish a *prima facie* case of obviousness:

> As is clear from cases such as *Adams,* a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (emphasis added).

Instead, the Court has made clear that the Examiner must establish a reason one of skill in the art would have combined the elements of the prior art, and that such reason must be more than a conclusory statement that it would have been obvious.

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine <u>whether there was an apparent reason to combine the known elements in the fashion claimed</u> by the patent at issue. To facilitate review, this analysis should be made explicit. *See In re Kahn,* 441 F.3d 977, 988 (C.A.Fed.2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-1741 (2007) (emphasis added).

Claim 1, from which Claim 2 previously depended, has been canceled and replaced with Claim 32. Claim 2 has been amended to now depend from Claim 32. Claim 32 includes all limitations of previous Claim 1 and includes the limitation that the oxygen used to catalyze a reaction of glucose and oxygen is "from a biological fluid surrounding the membrane."

Claim 14, from which Claims 15-16, 18, and 21 previously depended, has been canceled and replaced with Claim 33. Claims 15-16, 18, and 21 have been amended to now depend from Claim 33. Claim 33 includes all limitations of previous Claim 14 and includes the limitation that the oxygen used to catalyze a reaction of glucose and oxygen is "from a biological fluid surrounding the membrane."

As noted above, Kusano's sensor uses oxygen "from the ambient air rather than from that from dissolved in the interstitial fluid." Kusano, at page 2. Sternberg is cited in the Office Action dated April 28 ("Office Action") for the teaching of a system that "consume[s] a range of enzyme mass from about 0.18-1.7 μg over 7 days of continuous operation." Office Action, at page 6. Sternberg does not teach a sensor capable of obtaining substantial linearity at glucose concentrations of up to about 400 mg/dL in biological fluid with an oxygen concentration of less than about 0.3 mg/L.

In the Office Action, the Examiner contends that it purportedly "would have been obvious for one of ordinary skill in the art at the time the invention was made to configure the sensor of

Kusano so that a range of enzyme mass from about 0.18-1.7 μg was consumed over 7 days of operation." *Id.*

The Patent Owner respectfully submits that combining the teachings of Kusano and Sternberg would not have arrived at the claimed invention. More specifically, if the "immobilized glucose oxidase" layer disclosed in Kusano (*e.g.*, Fig. 7) was replaced with the glucose oxidase layer disclosed in Sternberg, the modified Kusano device would still use oxygen "from the ambient air rather than from that from dissolved in the interstitial fluid." *See* Kusano, at page 2. Clearly, Sternberg does not cure this deficiency. For at least this reason, the Patent Owner respectfully submits that new Claim 33 is distinguished from the teachings of Kusano and Sternberg and that this obviousness rejection of Claims 2, 15, 16, 18, and 21 cannot stand. Accordingly, withdrawal of this obviousness rejection is respectfully requested.

C. <u>Claims 7, 8, 23, 27, and 29-31 are patentable over Kusano in view of Rhodes.</u>

Claims 7, 8, 23, 27, and 29-31 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Kusano in view of Rhodes. The Patent Owner respectfully traverses this obviousness rejection. The criteria for establishing a *prima facie* case of obviousness are set forth above.

In the Office Action, the Examiner contends that it purportedly "would have been obvious for one of ordinary skill in the art at the time the invention was made to configure Kusano to have the resistance domain taught by Rhodes." Office Action, at page 7. The Patent Owner respectfully disagrees.

Regarding Claims 7 and 8, which depend from previous Claim 1, the Patent Owner submits that there is no motivation to combine the teachings of Kusano and Rhodes, in the manner suggested by the Examiner. More specifically, the Patent Owner submits that there is no motivation to combine because it is not necessary to improve oxygen-to-glucose permeability ratio of the Kusano device. Even if one were to combine the teachings of Kusano and Rhodes, it would not have yielded predictable results and/or would have rendered the Kusano device unsuitable for its intended purpose. Namely, Kusano performs a very specific testing to determine a certain concentration percentage of a certain type of polyurethane suitable to obtain up to about 20 nA electrode output at 500 mg/dL with the Kusano-specific sensor design. Kusano, at pages

5-6. Replacement of the Kusano polyurethane membrane designed for the Kusano device with the Rhodes polyurethane designed for the Rhodes device—with the devices differing at least in electroactive surface area which would inevitably affect the signal output—would not have yielded predictable results and may have rendered the Kusano device unsuitable for its intended purpose, because it is unclear whether the Rhodes membrane would maintain up to about 20 nA electrode output at 500 mg/dL, as desired by Kusano.

Regarding Claims 27 and 29-31, which depend from new Claim 34, the Patent Owner submits that combining the teachings of Kusano and Rhodes in the manner suggested by the Examiner would not have been obvious to try. Kusano expressly teaches a sensor that uses oxygen "from the ambient air rather than from that from dissolved in the interstitial fluid." Kusano, at page 2. Because Kusano's sensor is continuously supplied with ambient oxygen through an air intake, Kusano's device seemingly has no need for a membrane—with a specific permeability to oxygen—for interfacing biological fluid. Furthermore, the Patent Owner submits that proposed modification of the Kusano device would not have necessarily led to a predictable result, nor would it have necessarily arrived at the claimed invention. It is widely recognized in the art that the oxygen level in ambient air is much greater than the oxygen level in *in vivo* biological fluid. As a result, even if the Kusano device is modified to have a certain resistance membrane, as proposed by the Examiner, the oxygen would seemingly diffuse from the air intake side of the membrane towards the biological fluid side, because diffusion is a spontaneous movement of particles from a region of high concentration to a region of low concentration. Finally, Even if one were to combine the teachings of Kusano and Rhodes, it would not have yielded predictable results and/or would not have rendered the Kusano device unsuitable for its intended purpose. Namely, Kusano performs a very specific testing to determine a certain concentration percentage of a certain type of polyurethane suitable to obtain up to about 20 nA electrode output at 500 mg/dL with the Kusano-specific sensor design. Kusano, at pages 5-6. Replacement of the Kusano polyurethane membrane designed for the Kusano device with the Rhodes polyurethane designed for the Rhodes device—with the devices differing at least in electroactive surface area which would inevitably affect the signal output—would not have yielded predictable results and may have rendered the Kusano device unsuitable for its intended purpose, because it is unclear whether the Rhodes membrane would maintain an electrode output

up to about 20 nA at 500 mg/dL, as desired by Kusano. For at least the foregoing reasons, the Patent Owner respectfully submits that new Claim 34 is distinguished from the teachings of Kusano and Rhodes and that this obviousness rejection of Claims 7, 8, 27, and 29-31 cannot stand. Accordingly, withdrawal of this obviousness rejection is respectfully requested.

D. Claim 17 is patentable over Kusano in view of Sternberg and Rhodes.

Claim 17 stands rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Kusano in view of Sternberg and further in view of Rhodes. The Patent Owner respectfully traverses this obviousness rejection. The criteria for establishing a *prima facie* case of obviousness are set forth above.

Claim 17 depends from previous Claim 14. It is unclear from the Office Action whether the Examiner intends to replace the membrane of Kusano with (a) the membrane of Sternberg, (b) the membrane of Rhodes, or (c) both the membrane of Sternberg and Rhodes. If (a), then the claimed permeability ratio is not taught. If (b), then the claimed enzyme consumption is not taught. If (c), the resulting device, namely, the Kusano device with the Sternberg enzyme layer and the Rhodes polyurethane resistance layer would (1) have not been obvious to try, (2) have yielded predictable results, and (3) have seemingly rendered the Kusano device unsuitable for its intended purpose. First, because the Kusano device has solved the oxygen problem using an "air intake," there would have been no motivation to replace the existing Kusano polyurethane membrane, specifically designed for Kusano device with the Rhodes' polyurethane resistance layer, which is designed with a specific permeability to oxygen. Second, because the Kusano device utilizes a specific polyurethane membrane designed for a signal output of up to about 20 nA at about 500 mg/dL, replacement with the enzyme and resistance layers taught by Sternberg and Rhodes, respectively, would have yielded unpredictable results and/or rendered the Kusano device unsuitable for its intended purpose, *i.e.*, at Kusano's preferred parameters, which include a signal output of up to about 20 nA at about 500 mg/dL. For the foregoing reasons, the Patent Owner submits that this obviousness rejection of Claim 17 is improper and thus should be withdrawn.

E. Claim 24 is patentable over Kusano in view of Rhodes and Sternberg.

Claim 24 stands rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Kusano in view of Rhodes and further in view of Sternberg. The Patent Owner respectfully traverses this obviousness rejection. The criteria for establishing a *prima facie* case of obviousness are set forth above.

Claim 24 depends from previous Claim 23. It is unclear from the Office Action whether the Examiner intends to replace the membrane of Kusano with (a) the membrane of Rhodes, (b) the membrane of Sternberg, or (c) both the membrane of Sternberg and Rhodes. If (a), then the claimed enzyme consumption is not taught. If (b), then the claimed sensitivity is not taught. If (c), the resulting device, namely, the Kusano device with the Sternberg enzyme layer and the Rhodes polyurethane resistance layer would (1) have not been obvious to try, (2) have yielded predictable results, and (3) have seemingly rendered the Kusano device unsuitable for its intended purpose. First, because the Kusano device has solved the oxygen problem using an "air intake," there would have been no motivation to replace the existing Kusano polyurethane membrane, specifically designed for Kusano device with the Rhodes' polyurethane resistance layer, which is designed with a specific permeability to oxygen. Second, because the Kusano device utilizes a specific polyurethane membrane designed for a signal output of up to about 20 nA at about 500 mg/dL, replacement with the enzyme and resistance layers taught by Sternberg and Rhodes, respectively, would have yielded unpredictable results and/or rendered the Kusano device unsuitable for its intended purpose, *i.e.*, at Kusano's preferred parameters, which include a signal output of up to about 20 nA at about 500 mg/dL. Finally, simply exchanging the polyurethane membrane of Rhodes with the polyurethane membrane of Kusano would not necessarily have resulted in a sensitivity within the claimed range. Sensitivity is affected by a number of factors. *See*, *e.g.*, Col. 31, Lns. 40-54 of the '352 Patent. At the very least, because the exposed electroactive surface areas of Kusano's and Rhodes's devices are significantly different, replacing the Kusano polyurethane membrane with the Rhodes polyurethane membrane would not have predictably nor likely resulted in a modified Kusano device with a sensitivity within the claimed range. For the foregoing reasons, the Patent Owner submits that this obviousness rejection of Claim 24 is improper and thus should be withdrawn.

F. Claim 1, 7, 8, 23, and 31 are patentable over Rhodes.

Claims 1, 7, 8, 23, and 31 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by Rhodes. The Patent Owner respectfully traverses this anticipatory rejection. The criteria for establishing anticipation are set forth above.

Claim 1, from which Claims 7 and 8 previously depended, has been canceled and replaced with Claim 32. Claims 7 and 8 have been amended to now depend from Claim 32. Claim 32 includes all limitations of previous Claim 1, including the limitation of "substantial linearity at glucose concentrations of up to about 400 mg/dL in the biological fluid with an oxygen concentration of less than about 0.3 mg/L."

Claim 23, from which Claim 31 previously depended, has been canceled and replaced with Claim 34. Claim 31 have been amended to now depend from Claim 34. Claim 34 includes all limitations of previous Claim 23, except the limitation of "substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L," which has been replaced with "substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.45 mg/L."

According to the Examiner, "Rhodes teaches recording glucose values at oxygen concentrations as low as approximately 0.1 mg/L (see page 10)." Office Action, at page 9. While this may be true, one cannot infer that a mere glucose value recording—which may be inaccurate—by a sensor corresponds to achievement of substantial linearity by that sensor. Indeed, as clearly shown in FIG. 7 of Rhodes, the sensor function (which corresponds to sensor linearity in the Rhodes experiment) starts to drop precipitously at about 0.5 mg/L O_2 concentration for the silicone membrane, at about 1 mg/L O_2 concentration for the control membrane, and at about 1.5 mg/L O_2 concentration for the polyurethane membrane. Accordingly, the Patent Owner submits that Rhodes does not teach a sensor capable of achieving substantial linearity at glucose concentrations of up to about 400 mg/dL in a biological fluid with an oxygen concentration of less than about 0.45 mg/L, as recited in Claim 34, let alone, an oxygen concentration of less than about 0.3 mg/L, as recited in Claim 32. For at least this reason, the Patent Owner submits that new Claims 32 and 34 are distinguished from Rhodes and that the anticipatory rejection of Claims 7, 8, and 31 cannot stand. Accordingly, withdrawal of this anticipatory rejection is respectfully requested.

H. New Claims 35-37 are patentable over Kusano, Sternberg, and Rhodes.

New claims 35, 36, and 37 each depend from Claim 34 and recite that the biological fluid has an oxygen concentration of less than about 0.4 mg/L, 0.35 mg/L, and 0.3 mg/L, respectively. The Patent Owner respectfully submits that these claims are distinguished from the cited art. Support for these limitations can be found, *e.g.*, in FIG. 29 of the '352 Patent.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Patent Owner is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Patent Owner reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child, or related prosecution history shall not reasonably infer that Patent Owner has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Patent Owner wishes to draw the Examiner's attention to the following applications of the present application's assignee.

Docket No.	**Serial No.**	**Title**	**Filed**
DEXCOM.9CPDVC	07/122395	BIOLOGICAL FLUID MEASURING DEVICE	11/19/1987
DEXCOM.9CPDCP	07/216683	BIOLOGICAL FLUID MEASURING DEVICE	7/7/1988
DEXCOM.008A	08/811473	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	3/4/1997
DEXCOM.008DV1	09/447227	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	11/22/1999
DEXCOM.8DVC1	09/489588	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	1/21/2000

DEXCOM.8DVCP1	09/636369	SYSTEMS AND METHODS FOR REMOTE MONITORING AND MODULATION OF MEDICAL DEVICES	8/11/2000
DEXCOM.006A	09/916386	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	7/27/2001
DEXCOM.007A	09/916711	SENSOR HEAD FOR USE WITH IMPLANTABLE DEVICE	7/27/2001
DEXCOM.8DVCP2	09/916858	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	7/27/2001
DEXCOM.010A	10/153356	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	5/22/2002
DEXCOM.024A	10/632537	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
DEXCOM.026A	10/633329	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
DEXCOM.016A	10/633367	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
DEXCOM.025A	10/633404	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
DEXCOM.011A	10/646333	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	8/22/2003
DEXCOM.012A	10/647065	POROUS MEMBRANES FOR USE WITH IMPLANTABLE DEVICES	8/22/2003
DEXCOM.027A	10/648849	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	8/22/2003
DEXCOM.8DVC1C1	10/657843	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	9/9/2003
DEXCOM.028A	10/695636	SILICONE COMPOSITION FOR BIOCOMPATIBLE MEMBRANE	10/28/2003
DEXCOM.006C1	10/768889	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	1/29/2004
DEXCOM.037A	10/789359	INTEGRATED DELIVERY DEVICE FOR CONTINUOUS GLUCOSE SENSOR	2/26/2004
DEXCOM.045A	10/838658	IMPLANTABLE ANALYTE SENSOR	5/3/2004
DEXCOM.044A	10/838909	IMPLANTABLE ANALYTE SENSOR	5/3/2004
DEXCOM.043A	10/838912	IMPLANTABLE ANALYTE SENSOR	5/3/2004

DEXCOM.012CP1	10/842716	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	5/10/2004
DEXCOM.8DV1CP	10/846150	ANALYTE MEASURING DEVICE	5/14/2004
DEXCOM.048A	10/885476	SYSTEMS AND METHODS FOR MANUFACTURE OF AN ANALYTE-MEASURING DEVICE INCLUDING A MEMBRANE SYSTEM	7/6/2004
DEXCOM.019A	10/896637	ROLLED ELECTRODE ARRAY AND ITS METHOD FOR MANUFACTURE	7/21/2004
DEXCOM.021A	10/896639	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	7/21/2004
DEXCOM.020A	10/896772	INCREASING BIAS FOR OXYGEN PRODUCTION IN AN ELECTRODE SYSTEM	7/21/2004
DEXCOM.023A	10/897312	ELECTRODE SYSTEMS FOR ELECTROCHEMICAL SENSORS	7/21/2004
DEXCOM.022A	10/897377	ELECTROCHEMICAL SENSORS INCLUDING ELECTRODE SYSTEMS WITH INCREASED OXYGEN GENERATION	7/21/2004
DEXCOM.030A	10/991353	AFFINITY DOMAIN FOR ANALYTE SENSOR	11/16/2004
DEXCOM.032A	10/991966	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	11/17/2004
DEXCOM.038A	11/004561	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	12/3/2004
DEXCOM.031A	11/007635	SYSTEMS AND METHODS FOR IMPROVING ELECTROCHEMICAL ANALYTE SENSORS	12/7/2004
DEXCOM.029A	11/007920	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	12/8/2004
DEXCOM.008DV1C	11/021046	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	12/22/2004
DEXCOM.007C1	11/021162	SENSOR HEAD FOR USE WITH IMPLANTABLE DEVICES	12/22/2004
DEXCOM.040A	11/034343	COMPOSITE MATERIAL FOR IMPLANTABLE DEVICE	1/11/2005
DEXCOM.039A	11/034344	IMPLANTABLE DEVICE WITH IMPROVED RADIO FREQUENCY CAPABILITIES	1/11/2005

DEXCOM.024C1	11/038340	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	1/18/2005
DEXCOM.8DVCP2C	11/039269	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	1/19/2005
DEXCOM.034A	11/055779	BIOINTERFACE MEMBRANE WITH MACRO- AND MICRO-ARCHITECTURE	2/9/2005
DEXCOM.051A8	11/077643	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A5	11/077693	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A4	11/077713	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A6	11/077714	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A	11/077715	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A10	11/077739	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A11	11/077740	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.050A	11/077759	TRANSCUTANEOUS MEDICAL DEVICE WITH VARIABLE STIFFNESS	3/10/2005
DEXCOM.051A7	11/077763	METHOD AND SYSTEMS FOR INSERTING A TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A12	11/077765	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A1	11/077883	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A9	11/078072	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A2	11/078230	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A3	11/078232	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.061A1	11/157365	TRANSCUTANEOUS ANALYTE SENSOR	6/21/2005
DEXCOM.061A	11/157746	TRANSCUTANEOUS ANALYTE SENSOR	6/21/2005
DEXCOM.061A2	11/158227	TRANSCUTANEOUS ANALYTE SENSOR	6/21/2005

DEXCOM.016C1	11/201445	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/10/2005
DEXCOM.010DV2	11/280102	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	11/16/2005
DEXCOM.010DV1	11/280672	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	11/16/2005
DEXCOM.063A	11/333837	LOW OXYGEN IN VIVO ANALYTE SENSOR	1/17/2006
DEXCOM.061CP1	11/334107	TRANSCUTANEOUS ANALYTE SENSOR	1/17/2006
DEXCOM.061CP2	11/334876	TRANSCUTANEOUS ANALYTE SENSOR	1/18/2006
DEXCOM.058A	11/335879	CELLULOSIC-BASED INTERFERENCE DOMAIN FOR AN ANALYTE SENSOR	1/18/2006
DEXCOM.077A	11/360250	ANALYTE SENSOR	2/22/2006
DEXCOM.061CP3	11/360252	ANALYTE SENSOR	2/22/2006
DEXCOM.051CP1	11/360262	ANALYTE SENSOR	2/22/2006
DEXCOM.051CP2	11/360299	ANALYTE SENSOR	2/22/2006
DEXCOM.061CP4	11/360819	ANALYTE SENSOR	2/22/2006
DEXCOM.053A	11/373628	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA FOR SENSOR CALIBRATION	3/9/2006
DEXCOM.075A	11/404417	SILICONE BASED MEMBRANES FOR USE IN IMPLANTABLE GLUCOSE SENSORS	4/14/2006
DEXCOM.010CP1	11/404418	SILICONE BASED MEMBRANES FOR USE IN IMPLANTABLE GLUCOSE SENSORS	4/14/2006
DEXCOM.054A1	11/404421	ANALYTE SENSING BIOINTERFACE	4/14/2006
DEXCOM.054A	11/404929	ANALYTE SENSING BIOINTERFACE	4/14/2006
DEXCOM.054A2	11/404946	ANALYTE SENSING BIOINTERFACE	4/14/2006
DEXCOM.021C1	11/410392	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	4/25/2006
DEXCOM.021DV1	11/410555	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	4/25/2006
DEXCOM.051CP1C1	11/411656	ANALYTE SENSOR	4/26/2006

DEXCOM.060A	11/413238	CELLULOSIC-BASED RESISTANCE DOMAIN FOR AN ANALYTE SENSOR	4/28/2006
DEXCOM.060A2	11/413242	CELLULOSIC-BASED RESISTANCE DOMAIN FOR AN ANALYTE SENSOR	4/28/2006
DEXCOM.060A1	11/413356	CELLULOSIC-BASED RESISTANCE DOMAIN FOR AN ANALYTE SENSOR	4/28/2006
DEXCOM.051C1	11/415593	TRANSCUTANEOUS ANALYTE SENSOR	5/2/2006
DEXCOM.011DV3	11/415631	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	5/2/2006
DEXCOM.051C3	11/415999	TRANSCUTANEOUS ANALYTE SENSOR	5/2/2006
DEXCOM.011DV1	11/416058	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	5/2/2006
DEXCOM.011DV2	11/416346	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	5/2/2006
DEXCOM.051C2	11/416375	TRANSCUTANEOUS ANALYTE SENSOR	5/2/2006
DEXCOM.012CP1C2	11/416734	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	5/3/2006
DEXCOM.012CP1C1	11/416825	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	5/3/2006
DEXCOM.051CP4	11/439559	ANALYTE SENSOR	5/23/2006
DEXCOM.051CP3	11/439630	ANALYTE SENSOR	5/23/2006
DEXCOM.051CP5	11/439800	ANALYTE SENSOR	5/23/2006
DEXCOM.61CP3CP1	11/445792	ANALYTE SENSOR	6/1/2006
DEXCOM.027CP1	11/498410	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	8/2/2006
DEXCOM.51CP3CP1	11/503367	ANALYTE SENSOR	8/10/2006
DEXCOM.27CP1CP2	11/515342	SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	9/1/2006
DEXCOM.27CP1CP1	11/515443	SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	9/1/2006
DEXCOM.088A	11/543396	ANALYTE SENSOR	10/4/2006
DEXCOM.088A3	11/543404	ANALYTE SENSOR	10/4/2006
DEXCOM.088A2	11/543490	ANALYTE SENSOR	10/4/2006

DEXCOM.038CP2	11/543539	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
DEXCOM.038CP3	11/543683	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
DEXCOM.038CP1	11/543707	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
DEXCOM.038CP4	11/543734	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
DEXCOM.8DCP2CC1	11/546157	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	10/10/2006
DEXCOM.012DV1	11/654135	POROUS MEMBRANES FOR USE WITH IMPLANTABLE DEVICES	1/17/2007
DEXCOM.058CP1	11/654140	MEMBRANES FOR AN ANALYTE SENSOR	1/17/2007
DEXCOM.058CP2	11/654327	MEMBRANES FOR AN ANALYTE SENSOR	1/17/2007
DEXCOM.021CP1	11/675063	ANALYTE SENSOR	2/14/2007
DEXCOM.51CP1CP1	11/681145	ANALYTE SENSOR	3/1/2007
DEXCOM.61CP2CP1	11/690752	TRANSCUTANEOUS ANALYTE SENSOR	3/23/2007
DEXCOM.088CP3	11/691424	ANALYTE SENSOR	3/26/2007
DEXCOM.088CP1	11/691426	ANALYTE SENSOR	3/26/2007
DEXCOM.088CP2	11/691432	ANALYTE SENSOR	3/26/2007
DEXCOM.088CP4	11/691466	ANALYTE SENSOR	3/26/2007
DEXCOM.38CP1CP1	11/692154	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	3/27/2007
DEXCOM.61CP2CP4	11/734178	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2007
DEXCOM.61CP2CP2	11/734184	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2007
DEXCOM.61CP2CP3	11/734203	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2007
DEXCOM.093A	11/750907	ANALYTE SENSORS HAVING A SIGNAL-TO-NOISE RATIO SUBSTANTIALLY UNAFFECTED BY NON-CONSTANT NOISE	5/18/2007
DEXCOM.27CP1CP3	11/762638	SYSTEMS AND METHODS FOR REPLACING SIGNAL DATA ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	6/13/2007
DEXCOM.028DV1	11/763215	SILICONE COMPOSITION FOR BIOCOMPATIBLE MEMBRANE	6/14/2007

DEXCOM.051C4	11/797520	TRANSCUTANEOUS ANALYTE SENSOR	5/3/2007
DEXCOM.051C5	11/797521	TRANSCUTANEOUS ANALYTE SENSOR	5/3/2007
DEXCOM.061CP2C2	11/842139	TRANSCUTANEOUS ANALYTE SENSOR	8/21/2007
DEXCOM.061C1	11/842142	TRANSCUTANEOUS ANALYTE SENSOR	8/21/2007
DEXCOM.61CP2CPC	11/842143	TRANSCUTANEOUS ANALYTE SENSOR	8/20/2007
DEXCOM.061CP4C1	11/842146	ANALYTE SENSOR	8/20/2007
DEXCOM.061A1C1	11/842148	TRANSCUTANEOUS ANALYTE SENSOR	8/21/2007
DEXCOM.61CP3CPC	11/842149	TRANCUTANEOUS ANALYTE SENSOR	8/21/2007
DEXCOM.077C1	11/842151	ANALYTE SENSOR	8/21/2007
DEXCOM.061CP2C1	11/842154	TRANSCUTANEOUS ANALYTE SENSOR	8/21/2007
DEXCOM.093C1	11/842156	ANALYTE SENSORS HAVING A SIGNAL-TO-NOISE RATIO SUBSTANTILALLY UNAFFECTED BY NON-CONSTANT NOISE	8/21/2007
DEXCOM.51P3P1C1	11/842157	ANALYTE SENSOR	8/21/2007
DEXCOM.096A	11/855101	TRANSCUTANEOUS ANALYTE SENSOR	9/13/2007
DEXCOM.38CP1CP2	11/865572	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/1/2007
DEXCOM.025C1	11/865660	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	10/1/2007
DEXCOM.051A7C1	11/925603	TRANSCUTANEOUS ANALYTE SENSOR	10/26/2007
DEXCOM.8DV1CPD2	12/037812	ANALYTE MEASURING DEVICE	2/26/2008
DEXCOM.8DV1CPD1	12/037830	ANALYTE MEASURING DEVICE	2/26/2008
DEXCOM.107A	12/054953	ANALYTE SENSOR	3/25/2008
DEXCOM.88CP1CP2	12/055078	ANALYTE SENSOR	3/25/2008
DEXCOM.106A	12/055098	SYSTEM FOR PROCESSING SIGNALS FROM TWO IN VIVO ANALYTE SENSOR SENSORS	3/25/2008
DEXCOM.88CP1CP1	12/055114	ANALYTE SENSOR	3/25/2008
DEXCOM.88CP1CP3	12/055149	ANALYTE SENSOR	3/25/2008
DEXCOM.88CP1CP4	12/055203	ANALYTE SENSOR	3/25/2008

DEXCOM.88CP1CP5	12/055227	ANALYTE SENSOR	3/25/2008
DEXCOM.024C1D2	12/098353	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/4/2008
DEXCOM.024C1D1	12/098359	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/4/2008
DEXCOM.024C1D3	12/098627	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/7/2008
DEXCOM.051A6C3	12/101790	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2008
DEXCOM.051A9C1	12/101806	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2008
DEXCOM.051A6C2	12/101810	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2008
DEXCOM.016DV1	12/102654	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/14/2008
DEXCOM.016DV2	12/102729	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/14/2008
DEXCOM.016DV3	12/102745	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/14/2008
DEXCOM.034DV1	12/103594	BIOINTERFACE WITH MACRO- AND MICRO-ARCHITECTURE	4/15/2008
DEXCOM.050C1	12/105227	TRANSCUTANEOUS MEDICAL DEVICE WITH VARIABLE STIFFNESS	4/17/2008
DEXCOM.038CP3C1	12/111062	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	4/28/2008
DEXCOM.063C2	12/113508	LOW OXYGEN IN VIVO ANALYTE SENSOR	5/1/2008
DEXCOM.063C1	12/113724	LOW OXYGEN IN VIVO ANALYTE SENSOR	5/1/2008
DEXCOM.094A2	12/133738	INTEGRATED MEDICAMENT DELIVERY DEVICE FOR USE WITH CONTINUOUS ANALYTE SENSOR	6/5/2008
DEXCOM.094A3	12/133761	INTEGRATED MEDICAMENT DELIVERY DEVICE FOR USE WITH CONTINUOUS ANALYTE SENSOR	6/5/2008
DEXCOM.094A4	12/133786	INTEGRATED MEDICAMENT DELIVERY DEVICE FOR USE WITH CONTINUOUS ANALYTE SENSOR	6/5/2008

DEXCOM.037CP1	12/133820	INTEGRATED MEDICAMENT DELIVERY DEVICE FOR USE WITH CONTINUOUS ANALYTE SENSOR	6/5/2008
DEXCOM.061A2DV1	12/137396	TRANSCUTANEOUS ANALYTE SENSOR	6/11/2008
DEXCOM.023RE	12/139305	ELECTRODE SYSTEMS FOR ELECTROCHEMICAL SENSORS	6/13/2008
DEXCOM.051A8C1	12/175391	TRANSCUTANEOUS ANALYTE SENSOR	7/17/2008
DEXCOM.032DV2	12/182008	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	7/29/2008
DEXCOM.032C1	12/182073	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	7/29/2008
DEXCOM.032DV3	12/182083	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	7/29/2008
DEXCOM.025C1C2	12/195191	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/20/2008
DEXCOM.025C1C1	12/195773	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/21/2008
DEXCOM.045DV1	12/247137	IMPLANTABLE ANALYTE SENSOR	10/7/2008
DEXCOM.051CP3DV	12/250918	ANALYTE SENSOR	10/14/2008
DEXCOM.029DV2	12/252952	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.029DV5	12/252967	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.029DV1	12/252996	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.029DV6	12/253064	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.029DV3	12/253120	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.029DV4	12/253125	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.098A	12/258235	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.099A2	12/258318	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.016CP1	12/258320	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.099A1	12/258325	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008

DEXCOM.27CP1CP4	12/258335	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.099A	12/258345	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.007C1DV1	12/260017	SENSOR HEAD FOR USE WITH IMPLANTABLE DEVICES	10/28/2008
DEXCOM.029C1	12/263993	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	11/3/2008
DEXCOM.38CPCPDV	12/264160	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	11/3/2008
DEXCOM.043DV1	12/264835	IMPLANTABLE ANALYTE SENSOR	11/4/2008
DEXCOM.88CPP5P6	12/267494	INTEGRATED DEVICE FOR CONTINUOUS IN VIVO ANALYTE DETECTION AND SIMULTANEOUS CONTROL OF AN INFUSION DEVICE	11/7/2008
DEXCOM.038CP5	12/267518	ANALYTE SENSOR	11/7/2008
DEXCOM.88CP1P1P	12/267525	ANALYTE SENSOR	11/7/2008
DEXCOM.88P1P1P2	12/267531	ANALYTE SENSOR	11/7/2008
DEXCOM.016CP2	12/267542	ANALYTE SENSOR	11/7/2008
DEXCOM.88CPP5P4	12/267544	ANALYTE SENSOR	11/7/2008
DEXCOM.88CPP5P5	12/267545	ANALYTE SENSOR	11/7/2008
DEXCOM.88CPP5P3	12/267546	ANALYTE SENSOR	11/7/2008
DEXCOM.88CPP5P2	12/267547	ANALYTE SENSOR	11/7/2008
DEXCOM.88CPP5P1	12/267548	ANALYTE SENSOR	11/7/2008
DEXCOM.051A12C1	12/273359	TRANSCUTANEOUS ANALYTE SENSOR	11/18/2008
DEXCOM.051C6	12/329496	TRANSCUTANEOUS ANALYTE SENSOR	12/5/2008
DEXCOM.038CP2C1	12/335403	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	12/15/2008
DEXCOM.027DV1	12/353787	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/14/2009
DEXCOM.027DV2	12/353799	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/14/2009
DEXCOM.061C2	12/353870	TRANSCUTANEOUS ANALYTE SENSOR	1/14/2009
DEXCOM.051C7	12/359207	TRANSCUTANEOUS ANALYTE SENSOR	1/23/2009
DEXCOM.100A	12/362194	CONTINUOUS CARDIAC MARKER SENSOR SYSTEM	1/29/2009

DEXCOM.061CP2C3	12/364786	TRANSCUTANEOUS ANALYTE SENSOR	2/3/2009
DEXCOM.101A	12/365683	CONTINUOUS MEDICAMENT SENSOR SYSTEM FOR IN VIVO USE	2/4/2009
DEXCOM.102A2	12/390205	SYSTEMS AND METHODS FOR CUSTOMIZING DELIVERY OF SENSOR DATA	2/20/2009
DEXCOM.102A3	12/390290	SYSTEMS AND METHODS FOR BLOOD GLUCOSE MONITORING AND ALERT DELIVERY	2/20/2009
DEXCOM.102A1	12/390304	SYSTEMS AND METHODS FOR PROCESSING, TRANSMITTING AND DISPLAYING SENSOR DATA	2/20/2009
DEXCOM.061DV1	12/391148	TRANSCUTANEOUS ANALYTE SENSOR	2/23/2009
DEXCOM.051C10	12/393887	TRANSCUTANEOUS ANALYTE SENSOR	2/26/2009
DEXCOM.104A2	12/413166	POLYMER MEMBRANES FOR CONTINUOUS ANALYTE SENSORS	3/27/2009
DEXCOM.104A1	12/413231	POLYMER MEMBRANES FOR CONTINUOUS ANALYTE SENSORS	3/27/2009
DEXCOM.029DV8	12/424391	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	4/15/2009
DEXCOM.029DV7	12/424403	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	4/15/2009
DEXCOM.061A1C2	12/437436	TRANSCUTANEOUS ANALYTE SENSOR	5/7/2009
DEXCOM.029DV9	12/509396	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	7/24/2009
DEXCOM.075DV1	12/511982	SILICONE BASED MEMBRANES FOR USE IN IMPLANTABLE GLUCOSE SENSORS	7/29/2009
DEXCOM.088CP4C1	12/535620	ANALYTE SENSOR	8/4/2009
DEXCOM.037DV1	12/536852	INTEGRATED DELIVERY DEVICE FOR CONTINUOUS GLUCOSE SENSOR	8/6/2009
DEXCOM.095A	12/562011	PARTICLE-CONTAINING MEMBRANE AND PARTICULATE ELECTRODE FOR ANALYTE SENSORS	9/17/2009
DEXCOM.029DV11	12/565156	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV12	12/565166	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV13	12/565173	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009

DEXCOM.029DV10	12/565180	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV14	12/565199	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.032DV1DV	12/565205	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV15	12/565231	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV16	12/577668	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/12/2009
DEXCOM.029C4	12/577690	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/12/2009
DEXCOM.029DV17	12/577691	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/12/2009
DEXCOM.027C1	12/579339	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C3	12/579357	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C2	12/579363	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C7	12/579374	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C4	12/579385	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C5	12/579388	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C6	12/579392	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.044DV1	12/608872	IMPLANTABLE ANALYTE SENSOR	10/29/2009
DEXCOM.040DV1	12/610127	COMPOSITE MATERIAL FOR IMPLANTABLE DEVICE	10/30/2009
DEXCOM.061CP3C1	12/610866	ANALYTE SENSOR	11/2/2009
DEXCOM.038C1	12/619502	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	11/16/2009
DEXCOM.104C1	12/628095	POLYMER MEMBRANES FOR CONTINUOUS ANALYTE SENSORS	11/30/2009
DEXCOM.088CP3C2	12/630628	ANALYTE SENSOR	12/3/2009

DEXCOM.006C1C1	12/633578	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	12/8/2009
DEXCOM.025C1C3	12/633654	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/8/2009
DEXCOM.025C1C6	12/636473	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.025C1C9	12/636494	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.025C1C8	12/636540	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.025C1C5	12/636551	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.025C1C7	12/636574	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.025C1C4	12/636584	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.016C2	12/639746	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/16/2009
DEXCOM.026C1	12/639829	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/16/2009
DEXCOM.008DV1C3	12/645097	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	12/22/2009
DEXCOM.008DV1C2	12/645270	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	12/22/2009
DEXCOM.053C2	12/683724	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA FOR SENSOR CALIBRATION	1/7/2010
DEXCOM.053C1	12/683755	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA FOR SENSOR CALIBRATION	1/7/2010
DEXCOM.010DV1C1	12/688737	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	1/15/2010
DEXCOM.021C1C1	12/688763	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	1/15/2010

DEXCOM.026DV1	12/690792	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	1/20/2010
DEXCOM.058C1	12/691617	CELLULOSIC-BASED INTERFERENCE DOMAIN FOR AN ANALYTE SENSOR	1/21/2010
DEXCOM.8DCP2CCC	12/696003	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	1/28/2010
DEXCOM.088CP2C1	12/713607	ANALYTE SENSOR	2/26/2010
DEXCOM.104A1CP1	12/718299	POLYMER MEMBRANES FOR CONTINUOUS ANALYTE SENSORS	3/5/2010
DEXCOM.104A1CP2	12/718332	POLYMER MEMBRANES FOR CONTINUOUS ANALYTE SENSORS	3/5/2010
DEXCOM.051A6C4	12/728032	TRANSCUTANEOUS ANALYTE SENSOR	3/19/2010
DEXCOM.051A6C5	12/728060	TRANSCUTANEOUS ANALYTE SENSOR	3/19/2010
DEXCOM.051A6C6	12/728061	TRANSCUTANEOUS ANALYTE SENSOR	3/19/2010
DEXCOM.051A6C7	12/728082	TRANSCUTANEOUS ANALYTE SENSOR	3/19/2010
DEXCOM.51A8C1C1	12/729035	TRANSCUTANEOUS ANALYTE SENSOR	3/22/2010
DEXCOM.51A8C1C2	12/729048	TRANSCUTANEOUS ANALYTE SENSOR	3/22/2010
DEXCOM.051A10C1	12/729058	TRANSCUTANEOUS ANALYTE SENSOR	3/22/2010
DEXCOM.016C3	12/730058	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.051A10C2	12/730072	TRANSCUTANEOUS ANALYTE SENSOR	3/23/2010
DEXCOM.016C4	12/730077	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.016C6	12/730108	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.016C8	12/730123	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.016C9	12/730132	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010

DEXCOM.016C7	12/730144	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.016C5	12/730152	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.029C5	12/731046	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	3/24/2010
DEXCOM.032C1C1	12/731965	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	3/25/2010
DEXCOM.027C8	12/731980	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	3/25/2010
DEXCOM.27CPCPC1	12/732010	SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/25/2010
DEXCOM.27CPCP3C	12/732097	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	3/25/2010
DEXCOM.038CP2CC	12/748024	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	3/26/2010
DEXCOM.135A	12/748069	METHODS AND SYSTEMS FOR PROMOTING GLUCOSE MANAGEMENT	3/26/2010
DEXCOM.016C10	12/748144	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/26/2010
DEXCOM.053C3	12/748154	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA FOR SENSOR CALIBRATION	3/26/2010
DEXCOM.061A1C3	12/749139	TRANSCUTANEOUS ANALYTE SENSOR	3/29/2010
DEXCOM.38CPCPC2	12/749265	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	3/29/2010
DEXCOM.051A9C3	12/749981	TRANSCUTANEOUS ANALYTE SENSOR	3/30/2010
DEXCOM.038C3	12/760358	CALIBRATION TECHNIQUES FOR CONTINUOUS ANALYTE SENSOR	4/14/2010
DEXCOM.038C2	12/760432	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	4/14/2010
DEXCOM.8DV1C2C1	12/763013	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	4/19/2010
DEXCOM.8DV1C2C2	12/763016	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	4/19/2010

DEXCOM.138A	12/770618	PERFORMANCE REPORTS ASSOCIATED WITH CONTINUOUS SENSOR DATA FROM MULTIPLE ANALYSIS TIME PERIODS	4/29/2010
DEXCOM.016C12	12/772842	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/3/2010
DEXCOM.016C11	12/772849	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/3/2010
DEXCOM.051A5C1	12/775315	TRANSCUTANEOUS ANALYTE SENSOR	5/6/2010
DEXCOM.051A12C4	12/780606	TRANSCUTANEOUS ANALYTE SENSOR	5/14/2010
DEXCOM.051A12C2	12/780723	TRANSCUTANEOUS ANALYTE SENSOR	5/14/2010
DEXCOM.051A12C3	12/780725	TRANSCUTANEOUS ANALYTE SENSOR	5/14/2010
DEXCOM.051A12C5	12/780739	TRANSCUTANEOUS ANALYTE SENSOR	5/14/2010
DEXCOM.051A12C6	12/780759	TRANSCUTANEOUS ANALYTE SENSOR	5/14/2010
DEXCOM.027C9	12/787217	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	5/25/2010
DEXCOM.016C13	12/788125	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/26/2010
DEXCOM.027C10	12/789153	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	5/27/2010
DEXCOM.027C11	12/791686	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	6/1/2010
DEXCOM.027C12	12/791791	SYSTEM AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	6/1/2010
DEXCOM.88PP5P5P	12/828967	HOUSING FOR AN INTRAVASCULAR SENSOR	7/1/2010
DEXCOM.156A	12/829264	ANALYTE SENSOR	7/1/2010
DEXCOM.111A	12/829296	ANALYTE SENSORS AND METHODS OF MANUFACTURING SAME	7/1/2010
DEXCOM.111A3	12/829306	ANALYTE SENSORS AND METHODS OF MANUFACTURING SAME	7/1/2010

DEXCOM.111A2	12/829318	ANALYTE SENSORS AND METHODS OF MANUFACTURING SAME	7/1/2010
DEXCOM.157A3	12/829337	CONTINUOUS ANALYTE SENSORS AND METHODS OF MAKING SAME	7/1/2010
DEXCOM.157A	12/829339	CONTINUOUS ANALYTE SENSORS AND METHODS OF MAKING SAME	7/1/2010
DEXCOM.157A2	12/829340	CONTINUOUS ANALYTE SENSORS AND METHODS OF MAKING SAME	7/1/2010
DEXCOM.38CPCPC1	12/838691	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	7/19/2010
DEXCOM.038CP4RE	12/839260	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	7/19/2010
DEXCOM.061CP2C4	12/853235	TRANSCUTANEOUS ANALYTE SENSOR	8/9/2010
DEXCOM.096C1	12/869996	TRANSCUTANEOUS ANALYTE SENSOR	8/27/2010
DEXCOM.038C1C2	12/874031	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	9/1/2010
DEXCOM.038C1C1	12/874045	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	9/1/2010
DEXCOM.102A1C3	12/880015	SYSTEMS AND METHODS FOR PROCESSING, TRANSMITTING AND DISPLAYING SENSOR DATA	9/10/2010
DEXCOM.102A1C2	12/880026	SYSTEMS AND METHODS FOR PROCESSING, TRANSMITTING AND DISPLAYING SENSOR DATA	9/10/2010
DEXCOM.102A1C1	12/880031	SYSTEMS AND METHODS FOR PROCESSING, TRANSMITTING AND DISPLAYING SENSOR DATA	9/10/2010
DEXCOM.159A	12/893850	TRANSCUTANEOUS ANALYTE SENSOR	9/29/2010
DEXCOM.38PPDC	12/916289	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/29/2010
DEXCOM.027D2C1	13/014910	SYSTEM AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/27/2011
DEXCOM.027D2C2	13/014929	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/27/2011
DEXCOM.027D2D1	13/015208	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/27/2011
DEXCOM.027D2D2	13/015245	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/27/2011

DEXCOM.011D3C1	13/015950	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	1/28/2011
DEXCOM.027C15	13/023776	SYSTEMS AND METHODS OF REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	2/9/2011
DEXCOM.027C14	13/023835	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	2/9/2011
DEXCOM.027C13	13/023879	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	2/9/2011
DEXCOM.027C16	13/024076	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	2/9/2011
DEXCOM.137A	13/026163	IMPROVED RECEIVERS FOR ANALYZING AND DISPLAYING SENSOR DATA	2/11/2011
DEXCOM.063C4	13/031063	LOW OXYGEN IN VIVO ANALYTE SENSOR	2/18/2011
DEXCOM.051A1C1	13/077884	TRANSCUTANEOUS ANALYTE SENSOR	3/31/2011
DEXCOM.027P2D1	13/080587	SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/5/2011
DEXCOM.051A1C2	13/086160	TRANSCUTANEOUS ANALYTE SENSOR	4/13/2011
DEXCOM.032C3	13/092538	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	4/22/2011
DEXCOM.061P2C5	13/116871	TRANSCUTANEOUS ANALYTE SENSOR	5/26/2011
DEXCOM.025C11	13/118915	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/31/2011
DEXCOM.026D2	13/149005	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/31/2011
DEXCOM.025C12	13/149035	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/31/2011
DEXCOM.051A6P1	13/157031	TRANSCUTANEOUS ANALYTE SENSOR	6/9/2011
DEXCOM.016DV3RX	90/010988	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/10/2010

DEXCOM.016DV2RX	90/011031	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	6/14/2010
DEXCOM.006ARX	90/011067	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	6/25/2010
DEXCOM.006C1RX	90/011080	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	7/2/2010
DEXCOM.051A7RX	90/011086	METHODS AND SYSTEMS FOR INSERTING A TRANSCUTANEOUS ANALYTE SENSOR	7/8/2010
DEXCOM.010X	90/011329	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	11/12/2010
DEXCOM.012X	90/011330	POROUS MEMBRANES FOR USE WITH IMPLANTABLE DEVICES	11/12/2010
DEXCOM.061P3X	90/011333	ANALYTE SENSOR	11/15/2010
DEXCOM.008D1C1X	90/011345	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	11/19/2010
DEXCOM.051X	90/011351	TRANSCUTANEOUS ANALYTE SENSOR	11/22/2010
DEXCOM.8D1C3X	90/011466	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	1/31/2011
DEXCOM.016AX	90/011467	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	1/31/2011
DEXCOM.63C2X	90/011468	LOW OXYGEN IN VIVO ANALYTE SENSOR	2/1/2011
DEXCOM.063X2	90/011610	LOW OXYGEN IN VIVO ANALYTE SENSOR	3/31/2011
DEXCOM.016X4	90/011635	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/8/2011
DEXCOM.031X1	90/011645	SYSTEMS AND METHODS FOR IMPROVING ELECTROCHECMICAL ANALYTE SENSORS	4/14/2011
DEXCOM.051A5X1	90/011663	TRANSCUTANEOUS ANALYTE SENSOR	4/29/2011
DEXCOM.038X1	90/011671	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	5/5/2011
DEXCOM.008X	90/011683	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	5/10/2011
DEXCOM.024X2	90/011721	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/31/2011

DEXCOM.008X2	90/011722	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	5/31/2011
DEXCOM.025RX	95/001038	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/17/2008
DEXCOM.024RX	95/001039	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/17/2008

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 28, 2011

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/011,468	02/01/2011	771352	ADCI-GEN51	9182

20995 7590 04/28/2011

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EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 04/28/2011

Please find below and/or attached an Office communication concerning this application or proceeding.

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East Palo Alto, CA 94303

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. 90/011,468.

PATENT NO. 771352.

ART UNIT 3993.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Order Granting / Denying Request For Ex Parte Reexamination	Control No. 90/011,468	Patent Under Reexamination 771352	
	Examiner BEVERLY M. FLANAGAN	Art Unit 3993	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The request for *ex parte* reexamination filed 01 February 2011 has been considered and a determination has been made. An identification of the claims, the references relied upon, and the rationale supporting the determination are attached.

Attachments: a)☐ PTO-892, b)☒ PTO/SB/08, c)☐ Other: _____

1. ☒ The request for *ex parte* reexamination is GRANTED.

AL 4/27/11

RESPONSE TIMES ARE SET AS FOLLOWS: AS IN ATTACHED ACTION.

~~For Patent Owner's Statement (Optional): TWO MONTHS from the mailing date of this communication (37 CFR 1.530 (b)). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**~~

~~For Requester's Reply (optional): TWO MONTHS from the **date of service** of any timely filed Patent Owner's Statement (37 CFR 1.535). **NO EXTENSION OF THIS TIME PERIOD IS PERMITTED.** If Patent Owner does not file a timely statement under 37 CFR 1.530(b), then no reply by requester is permitted.~~

2. ☐ The request for *ex parte* reexamination is DENIED.

This decision is not appealable (35 U.S.C. 303(c)). Requester may seek review by petition to the Commissioner under 37 CFR 1.181 within ONE MONTH from the mailing date of this communication (37 CFR 1.515(c)). **EXTENSION OF TIME TO FILE SUCH A PETITION UNDER 37 CFR 1.181 ARE AVAILABLE ONLY BY PETITION TO SUSPEND OR WAIVE THE REGULATIONS UNDER 37 CFR 1.183.**

In due course, a refund under 37 CFR 1.26 (c) will be made to requester:

a) ☐ by Treasury check or,

b) ☐ by credit to Deposit Account No. _____, or

c) ☐ by credit to a credit card account, unless otherwise notified (35 U.S.C. 303(c)).

cc:Requester (if third party requester)

DECISION ON REQUEST FOR REEXAMINATION

A substantial new question of patentability affecting claims 1-9, 12, 14-18, 21, 23, 24, 27 and 29-31 of United States Patent Number 7,771,352 is raised by the request for *ex parte* reexamination.

Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that *ex parte* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extensions of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

Service of Papers

After the filing of a request for reexamination by a third party requester, any document filed by either the patent owner or the third party requester must be served on the other party (or parties where two or more third party requester proceedings are merged) in the reexamination proceeding in the manner provided in 37 C.F.R. 1.248. See 37 C.F.R. 1.550(f).

Waiver of Right to File Patent Owner Statement

In a telephone interview on February 16, 2011, patent owner agreed to waive its right to file a patent owner's statement under 35 U.S.C. § 304 in the event reexamination was ordered for U.S. Patent No. 7,792,562.

Amendment in Reexamination Proceedings

Patent owner is notified that any proposed amendment to the specification and/or claims in this reexamination proceeding must comply with 37 C.F.R. 1.530(d)-(j), must be formally presented pursuant to 37 C.F.R. 1.52(a) and (b), and must contain any fees required by 37 C.F.R. 1.20(c).

Submissions

In order to ensure full consideration of any amendments, affidavits or declarations or other documents as evidence of patentability, such documents must be submitted in response to the first Office action on the merits (which does not result in a close of prosecution). Submissions after the second Office action on the merits, which is intended to be a final action, will be governed by the requirements of 37 C.F.R. 1.116, after final rejection and by 37 C.F.R. 41.33 after appeal, which will be strictly enforced.

Notification of Concurrent Proceedings

The patent owner is reminded of the continuing responsibility under 37 C.F.R. 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving U.S. Patent No. 7,771,352 throughout the course of this reexamination proceeding. Likewise, if present, the third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding

throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Substantial New Question

A substantial new question of patentability (SNQ) is based on the following newly submitted printed publications:

Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissolved oxygen, *Clin. Phys. Physiol. Meas.*, vol. 10, 1:1-9 (1989) (hereinafter "Kusano"); and

Sternberg et al., Covalent Enzyme Coupling on Cellulose Acetate Membranes for Glucose Sensor Development, *Anal. Chem.*, 60:2781-2786 (1988) (hereinafter "Sternberg").

A substantial new question of patentability (SNQ) is also based on the following previously-cited printed publications:

Rhodes et al., U.S. Patent Application Publication No. 20030032874 (hereinafter "Rhodes").

On November 2, 2002, Public Law 107-273 was enacted. Title III, Subtitle A, Section 13105, part (a) of the Act revised the reexamination statute by adding the following new last sentence to 35 U.S.C. 303(a) and 312(a):

"The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office."

For any reexamination ordered on or after November 2, 2002, the effective date of the statutory revision, reliance on previously cited/considered art, i.e., "old art," does not necessarily preclude the existence of a substantial new question of patentability (SNQ) that is based exclusively on that old art. Rather, determinations on whether a SNQ exists in such an instance shall be based upon a fact-specific inquiry. In the instant case Rhodes was cited in the previous examination, but was not applied to the claims. In addition, Rhodes was not considered in combination with Kusano and Sternberg, as is proposed in the instant request. This situation provides the new light under which the Rhodes reference is considered.

No SNQ Proposed or Raised

Requester lists a Kerner publication (Kerner et al., A Potentially Implantable Enzyme Electrode for Amperometric Measurement of Glucose, *Horm. Metab. Res. Suppl.*, 20:8-13 (1989) (hereinafter "Kerner")) on the information disclosure statement provided with the request. Requester does discuss this reference and its application to the claims under 35 U.S.C. §103 (see, e.g., pages 51-71 and Exhibit J of the request). However, requester does not propose *any* SNQ with respect to Kerner. 37 CFR 1.510(b)(1) requires that a request for *ex parte* reexamination include "a statement

pointing out each substantial new question of patentability based on the cited patents and printed publications." Requester has failed to provide this required statement with respect to Kerner.

Furthermore, an SNQ is not raised by the old prior art if the Office has previously considered (in an earlier examination of the patent) the <u>same</u> question of patentability as to the patent and has decided that question in favor of the patent owner based on the same prior art patents or printed publications. *In re Recreative Technologies*, 83 F.3d 1394, 38 USPQ2d 1776 (Fed. Cir. 1996).

Looking to the legislative history for the original reexamination statute,[1] Congress stated:

> "Section I provides for a system of administrative reexamination of patents within the patent office. This new procedure will permit any party to petition the patent office to review the efficacy of a patent, subsequent to its issuance, on the basis of **new information about preexisting technology which may have escaped review at the time of the initial examination of the patent application**. H.R. Rep. No. 96-1307, 96th Cong., 2d Sess. 3 (1980), reprinted in 1980 U.S.C.C.A.N. 6460, 6461, 6462." [Emphasis added]

Reexamination is limited to review of **new information** about preexisting **technology** that may have escaped review at the time of the initial examination of the patent application. It was not designed for harassment of a patent owner by review of old information about preexisting technology, even if a third party feels the Office's conclusion based on that old information was erroneous. The Office may assume jurisdiction over a patent for which reexamination is requested in order to review the patentability of one or more claims of that patent <u>only</u> if such new information about

preexisting technology is presented in a request for reexamination. Absent establishment of at least one SNQ, the Office does not have jurisdiction to revisit the issue of claim patentability.

In accordance with this legislative history, MPEP 2242, part II.A. was drafted to require, in order to raise a SNQ for old art, that the old art must be "presented/viewed in a new light, or in a different way, as compared with its use in the earlier concluded examination(s), in view of a material new argument or interpretation presented in the request." [2],[3] This new light must be in terms of how to interpret the state of the "pre-existing technology," as was envisioned by the authors of the original reexamination statute, and left unchanged by the 2002 enactment. For example, a reference may be read in a "new light" if the requester draws attention to a portion of the reference that was not relied upon, or otherwise addressed, in a rejection during the earlier concluded examination of the patent for which reexamination is requested. Similarly, a reference may be interpreted in a new light, or in a different way, by defining a term of art used in the reference, where the definition of the term of art had not been previously presented in the earlier concluded examination of the patent.

Notwithstanding the fact that no SNQ is proposed with respect to Kerner, the discussion of Kerner in the request at pages 44-71 fails to clearly and explicitly point to any new technical teaching presented by Kerner that was not considered in the prior

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[1] Public Law 96-517, enacted on December 12, 1980.

[2] See: *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351 (Bd. Pat. App. & Inter. 1984).

[3] For additional discussion regarding technical teachings viewed "in a new light, see: *In re Melvin J. Swanson et al*, 540 F.3d 1368,1376, 2008 U.S. APP. Lexis 18928, **16-17 (citing H.R. Rep. No. 96-1307 (1980) and H.R. Rep. No. 107-120, at 2-3

examination. Kerner was applied against the claims under 35 U.S.C. § 102(b) in the previous examination (see the Office action of February 23, 2010). Kerner was not applied against then pending claim 2, because it did not teach that the sensor electronics unit was configured to measure glucose in a fluid with an oxygen concentration of less than about 0.3 mg/L. Claim 2 was then made independent and allowed by the examiner. Requester discusses, as at page 45 of the request , combining Kerner and Kusano under 35 U.S.C. § 103. However, requester does not highlight or discuss any new technical teaching of Kerner that would result in the reference being considered in a "new light" pursuant to MPEP 2242.

For these reasons, the Kerner reference is determined by the examiner not to raise an SNQ.

A discussion of the specifics follows:

The Kusano Reference

It is agreed that the Kusano reference raises a SNQ as to claims 1-9, 12, 14-18, 21, 23, 24, 27 and 29-31 of U.S. Patent No. 7,771,352.

In regard to claims 1, 3-5, 7, 8, 12, 14-18, 21, 23, 24, 27 and 29-31, it is agreed that Kusano teaches an implantable body comprising an electrode configured to measure a glucose level in a host (see Fig. 3 and pages 2-3). Kusano teaches a membrane located over at least a portion of the electrode surface, the membrane comprising polyurethane and having a resistance domain configured to limit transport of

glucose to the electrode, including an enzyme configured to catalyze a reaction of glucose and oxygen (see Fig. 2 and pages 1-3). Kusano also teaches sensor electronics operably connected to the electrode. Kusano also teaches that the sensor system measures glucose concentrations from 0 to 500 mg/dL, in a fluid with an oxygen concentration ranging from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg) (see pages 6-7). Kusano also teaches that the electrode had a linear response to glucose concentration at an electrode output current ranging from 0 to 20nA even when the oxygen concentration of the glucose solution is zero (see Abstract and Fig. 8). Kusano also teaches that glucose concentrations of 0 to 500 mg/dL can be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (see page 8). oxygen concentration had no effect on electrode response (see pages 6-7 and Fig 8). ***In regard to claim 6***, Kusano teaches a working electrode with 0.5 µg of aluminum-linked glucose oxidase immobilized at the tip of a Pt wire 0.5 mm in diameter, making the electroactive surface (the surface area of the tip of the Pt wire) 0.000304 in^2 (area = πr^2 = $(3.14)(0.25\ mm)^2$ = 0.196 mm^2 = 0.000304 in^2) (see Abstract). ***In regard to claim 9***, Kusano teaches that the steady state current at a glucose concentration of 500 mg/dL should be less than the saturation current which results when the oxygen supplied from the air is limited, which is about 20nA in this electrode, thus teaching a sensitivity of less than 40 pA/mg/dL (see page 6).

The teachings identified above were not present in the prosecution of the application which became U.S. Patent No. 7,771,352. Accordingly, there is a substantial likelihood that a reasonable examiner would consider these teachings

important in deciding whether or not the claim is patentable. Thus, Kusano raises a substantial new question of patentability as to claims 1-9, 12, 14-18, 21, 23, 24, 27 and 29-31 which question has not been decided in a previous examination of U.S. Patent No. 7,771,352.

The Sternberg Reference

It is agreed that the Sternberg reference raises a SNQ as to claims 2, 14-16, 18 and 21 of U.S. Patent No. 7,771,352.

In regard to claims 2, 14-16, 18 and 21, it is agreed that Sternberg teaches three procedures for preparing electrodes with immobilized glucose oxidase (GOx)and examines time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface (see page 2784 and Fig. 5). Fig. 5 shows that the relative consumption of GOx over the first seven days of use is between about 10% and about 15%, resulting in a consumption of about 0.18-0.63 μg (prepared with procedure a), 0.42-1.3 μg (prepared with procedure b) and 0.86-1.7 μg (prepared with procedure c). Sternberg thus teaches how to configure a system to consume a range of enzyme mass from about 0.18-1.7 μg over 7 days of continuous operation.

The teachings identified above were present in the prosecution of the application which became U.S. Patent No. 7,792,562. However, they were not applied to the claims. There is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claim is patentable. Accordingly, Sternberg raises a substantial new question of patentability as to claims 2,

14-16, 18 and 21, which question has not been decided in a previous examination of U.S. Patent No. 7,771,352.

The Rhodes Reference

It is agreed that the Rhodes reference raises a SNQ as to claims 1, 7, 8, 17, 23, 27 and 29-31 of U.S. Patent No. 7,771,352.

In regard to claims 1, 23, 27, 29 and 30, it is agreed that Rhodes teaches a continuous glucose sensor system having an implantable body comprising an electrode configured to measure a glucose level in a host (see Abstract, page 2, paragraphs 0012-0017 and 0020). Rhodes also teaches a membrane disposed over the electrode that comprises a resistance domain configured to limit transport of glucose to the electrode (see page 5, paragraph 0062 to page 8, paragraph 0108 and Figs. 2A-2F). Rhodes also teaches an enzyme configured to catalyze a reaction of glucose and oxygen (see page 7, paragraphs 0086-0088). Rhodes also teaches sensor electronics operably connected to the electrode and that testing was conducted up to a glucose concentration of 400 mg/dL and that sensitivity of the sensor to glucose was given as the slope of sensor output versus glucose concentration (see page 10). Rhodes teaches recording glucose values at oxygen concentrations as low as approximately 0.1 mg/L (see page 10). ***In regard to claims 7, 8, 17 and 31***, Rhodes teaches oxygen-to-glucose permeability ratios of approximately 200:1 (see pages 6-7). ***With further respect to claim 23***, Rhodes teaches a sensor system configured to have a sensor output of at least 5.5 pA/mg/dL between 0-300 mg/dL (see Fig. 3).

The teachings identified above were present in the prosecution of the application which became U.S. Patent No. 7,792,562. However, they were not applied to the claims. There is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claim is patentable. Accordingly, Rhodes raises a substantial new question of patentability as to claims 1, 7, 8, 17, 23, 27 and 29-31, which question has not been decided in a previous examination of U.S. Patent No. 7,771,352.

Scope of Reexamination

Since requester did not request reexamination of claims 10, 11, 13, 19, 20, 22, 25, 26 and 28 and did not assert the existence of a substantial new question of patentability (SNQP) for such claims (see 35 U.S.C. § 311(b)(2); see also 37 CFR 1.915b and 1.923), such claims will not be reexamined. This matter was squarely addressed in *Sony Computer Entertainment America Inc., et al. v. Jon W. Dudas*, Civil Action No. 1:05CV1447 (E.D.Va. May 22, 2006), Slip Copy, 2006 WL 1472462. (Not Reported in F.Supp.2d.) The District Court upheld the Office's discretion to not reexamine claims in an *inter partes* reexamination proceeding other than those claims for which reexamination had specifically been requested. The Court stated:

> To be sure, a party may seek, and the PTO may grant, *inter partes* review of each and every claim of a patent. Moreover, while the PTO in its discretion may review claims for which *inter partes* review was not requested, nothing in the statute compels it to do so. To ensure that the PTO considers a claim for *inter partes* review, § 311(b)(2) requires that the party seeking reexamination demonstrate why the PTO should reexamine each and every claim for which it seeks review. Here, it is

> undisputed that Sony did not seek review of every claim under the '213 and '333 patents. Accordingly, Sony cannot now claim that the PTO wrongly failed to reexamine claims for which Sony never requested review, and its argument that AIPA compels a contrary result is unpersuasive.

(Slip copy at page 9.)

The *Sony* decision's reasoning and statutory interpretation apply analogously to *ex parte* reexamination, as the same relevant statutory language applies to both *inter partes* and *ex parte* reexamination. 35 U.S.C. § 302 provides that the *ex parte* reexamination "request must set forth the pertinency and manner of applying cited prior art to every claim for which reexamination is requested" (emphasis added), and 35 U.S.C. § 303 provides that "the Director will determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request..." (Emphasis added). These provisions are analogous to the language of 35 U.S.C. § 311(b)(2) and 35 U.S.C. § 312 applied and construed in *Sony*, and would be construed in the same manner. As the Director can decline to reexamine non-requested claims in an *inter partes* reexamination proceeding, the Director can likewise do so in *ex parte* reexamination proceeding. See *Notice of Clarification of Office Policy To Exercise Discretion in Reexamining Fewer Than All the Patent Claims* (signed Oct. 5, 2006) 1311 OG 197 (Oct. 31, 2006). See also MPEP § 2240, Rev. 5, Aug. 2006.

Therefore, claims 10, 11, 13, 19, 20, 22, 25, 26 and 28 will not be reexamined in this ex *partes* reexamination proceeding.

Conclusion

Please mail any communications to:

Attn: Mail Stop "Ex Parte Reexam"
Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Please FAX any communications to:

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Central Reexamination Unit

Please hand-deliver any communications to:

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Attn: Central Reexamination Unit
Randolph Building, Lobby Level
401 Dulaney Street
Alexandria, VA 22314

Any inquiry concerning this communication or earlier communications from the Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:

/Beverly M. Flanagan/

Beverly M. Flanagan
CRU Examiner
GAU 3993
(571) 272-4766

Conferee /JRJ/

Conferee AK ____________

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	90/011468
	Filing Date	02-01-2011
	First Named Inventor	Shults, Mark C.
	Art Unit	3993
(Multiple sheets used when necessary)	Examiner	Flanagan, Beverly M.
SHEET 1 OF 1	Attorney Docket No.	DEXCOM.63C2X

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
BF	1	6,893,552	05-17-2005	Wang et al.	
	2	7,899,511	03-01-2011	Shults, Mark et al.	
	3	7,901,354	03-08-2011	Shults, Mark et al.	
	4	2004-0173472	09-09-2004	Jung et al.	
	5	2009-0099434	04-16-2009	Liu et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]
BF	6	WO 01/020019	03-22-2001	Implanted Biosystems		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
BF	7	EPO Communication [DEXCOM.063VEP] dated February 26, 2010 in Application No. EP 06718980.3, filed 01/17/2006	

10961906:abt
032811

Examiner Signature	B. FLANAGAN	Date Considered	4/27/11

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T[1] - Place a check mark in this area when an English language Translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	
	Filing Date	2011-02-01
	First Named Inventor	Shults, Mark C.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	ADCI-GEN51

U.S.PATENTS

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
BT	1	20030032874		2003-02-13	Rhodes et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	
	Filing Date	2011-02-01
	First Named Inventor	Shults, Mark C.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	ADCI-GEN51

BF	1	Kerner, et al., A Potentially Implantable Enzyme Electrode for Amperometric Measurement of Glucose, Horm Metab Res Suppl., 20:8-13 (1989).	☐
	2	Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissolved oxygen, Clin. Phys. Physiol. Meas., vol. 10, 1:1-9 (1989).	☐
	3	Sternberg, et al., Covalent Enzyme Coupling on Cellulose Acetate Membranes for Glucose Sensor Development, Anal Chem., 60: 2781-2786 (1988).	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	B FLANAGAN	Date Considered	4/27/11

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/011,468	02/01/2011	771352	ADCI-GEN51	9182

20995 7590 04/28/2011

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	

ART UNIT	PAPER NUMBER

DATE MAILED: 04/28/2011

Please find below and/or attached an Office communication concerning this application or proceeding.

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(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

Abbott Diabetes Care Inc.

Bozicevic, Field & Francis, LLP

1900 University Avenue, Suite 200

East Palo Alto, CA 94303

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. *90/011,468*.

PATENT NO. *771352*.

ART UNIT *3993*.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Office Action in Ex Parte Reexamination	Control No. 90/011,468	Patent Under Reexamination 771352	
	Examiner BEVERLY M. FLANAGAN	Art Unit 3993	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

a☐ Responsive to the communication(s) filed on _____ . b☐ This action is made FINAL.
c☐ A statement under 37 CFR 1.530 has not been received from the patent owner.

A shortened statutory period for response to this action is set to expire 2 month(s) from the mailing date of this letter.
Failure to respond within the period for response will result in termination of the proceeding and issuance of an *ex parte* reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**
If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Information Disclosure Statement, PTO/SB/08.
3. ☐ Interview Summary, PTO-474.
4. ☐ _____.

Part II SUMMARY OF ACTION

1a. ☒ Claims *1-9,12,14-18,21,23,24,27 and 29-31* are subject to reexamination.
1b. ☒ Claims *10,11,13,19,20,22,25,26 and 28* are not subject to reexamination.
2. ☐ Claims _____ have been canceled in the present reexamination proceeding.
3. ☐ Claims _____ are patentable and/or confirmed.
4. ☒ Claims *1-9,12,14-18,21,23,24,27 and 29-31* are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ The drawings, filed on _____ are acceptable.
7. ☐ The proposed drawing correction, filed on _____ has been (7a)☐ approved (7b)☐ disapproved.
8. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
   a)☐ All b)☐ Some* c)☐ None of the certified copies have
   1☐ been received.
   2☐ not been received.
   3☐ been filed in Application No. _____ .
   4☐ been filed in reexamination Control No. _____.
   5☐ been received by the International Bureau in PCT application No. _____.
   * See the attached detailed Office action for a list of the certified copies not received.
9. ☐ Since the proceeding appears to be in condition for issuance of an *ex parte* reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.
10. ☐ Other: _____

cc: Requester (if third party requester)

DETAILED ACTION

Reexamination Procedures

In order to ensure full consideration of any amendments, affidavits or declarations, or other documents as evidence of patentability, such documents must be submitted in response to this Office action. Submissions after the next Office action, which is intended to be a final action, will be governed by the requirements of 37 C.F.R. 1.116, after final rejection and 37 C.F.R. 41.33 after appeal, which will be strictly enforced.

Extensions of time under 37 C.F.R. 1.136(a) will not be permitted in these proceedings because the provisions of 37 C.F.R. 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. § 305 requires that reexamination proceedings "will be conducted with special dispatch" (37 C.F.R. 1.550(a)). Extension of time in *ex parte* reexamination proceedings are provided for in 37 C.F.R. 1.550(c).

The patent owner is reminded of the continuing responsibility under 37 C.F.R. 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 7,771,352 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability of similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Patent owner is notified that any proposed amendment to the specification and/or claims in this reexamination proceeding must comply with 37 C.F.R. 1.530(d)-(j), must

be formally presented pursuant to 37 C.F.R. 1.52(a) and (b), and must contain any fees required by 37 C.F.R. 1.20(c).

After the filing of a request for reexamination by a third party requester, any document filed by either the patent owner or the third party requested must be served on the other party (or parties where two or more third party requested proceedings are merged) in the reexamination proceeding in the manner provided in 37 C.F.R. 1.248. See 37 C.F.R. 1.550(f).

Waiver of Right to File Patent Owner's Statement

In a telephone interview on February 16, 2011, patent owner agreed to waive its right to file a patent owner's statement under 35 U.S.C. § 304 in the event reexamination was ordered for U.S. Patent No. 7,771,352.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-6, 9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Kusano.

In regard to claims 1, 3-5 and 12, Kusano teaches an implantable body comprising an electrode configured to measure a glucose level in a host (see Fig. 3 and

pages 2-3). Kusano teaches a membrane located over at least a portion of the electrode surface, the membrane comprising polyurethane and having a resistance domain configured to limit transport of glucose to the electrode, including an enzyme configured to catalyze a reaction of glucose and oxygen (see Fig. 2 and pages 1-3). Kusano also teaches sensor electronics operably connected to the electrode. Kusano also teaches that the sensor system measures glucose concentrations from 0 to 500 mg/dL, in a fluid with an oxygen concentration ranging from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg) (see pages 6-7). Kusano also teaches that the electrode had a linear response to glucose concentration at an electrode output current ranging from 0 to 20nA even when the oxygen concentration of the glucose solution is zero (see Abstract and Fig. 8). Kusano also teaches that glucose concentrations of 0 to 500 mg/dL can be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (see page 8). oxygen concentration had no effect on electrode response (see pages 6-7 and Fig 8). ***In regard to claim 6***, Kusano teaches a working electrode with 0.5 μg of aluminum-linked glucose oxidase immobilized at the tip of a Pt wire 0.5 mm in diameter, making the electroactive surface (the surface area of the tip of the Pt wire) 0.000304 in^2 (area = πr^2 = (3.14)(0.25 mm)^2 = 0.196 mm^2 = 0.000304 in^2) (see Abstract). ***In regard to claim 9***, Kusano teaches that the steady state current at a glucose concentration of 500 mg/dL should be less than the saturation current which results when the oxygen supplied from the air is limited, which is about 20nA in this electrode, thus teaching a sensitivity of less than 40 pA/mg/dL (see page 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 14-16, 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kusano in view of Sternberg.

In regard to claims 14-16, 18 and 21, Kusano teaches an implantable body comprising an electrode configured to measure a glucose level in a host (see Fig. 3 and pages 2-3). Kusano teaches a membrane located over at least a portion of the electrode surface, the membrane comprising polyurethane and having a resistance domain configured to limit transport of glucose to the electrode, including an enzyme configured to catalyze a reaction of glucose and oxygen (see Fig. 2 and pages 1-3). Kusano also teaches sensor electronics operably connected to the electrode. Kusano also teaches that the sensor system measures glucose concentrations from 0 to 500 mg/dL, in a fluid with an oxygen concentration ranging from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg) (see pages 6-7). Kusano also teaches that the electrode had a linear response to glucose concentration at an electrode output current ranging from 0 to 20nA even when the oxygen concentration of the glucose solution is zero (see Abstract and Fig. 8). Kusano also teaches that glucose concentrations of 0 to 500 mg/dL can be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (see page 8). oxygen concentration had no effect on electrode response (see

pages 6-7 and Fig 8). ***With further respect to claim 14 and in regard to claim 2,*** Kusano is silent as to less than about 1 µg of enzyme being consumed over 7 days of continuous operation. However, Sternberg teaches three procedures for preparing electrodes with immobilized glucose oxidase (GOx)and examines time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface (see page 2784 and Fig. 5). Fig. 5 shows that the relative consumption of GOx over the first seven days of use is between about 10% and about 15%, resulting in a consumption of about 0.18-0.63 µg (prepared with procedure a), 0.42-1.3 µg (prepared with procedure b) and 0.86-1.7 µg (prepared with procedure c). Sternberg thus teaches how to configure a system to consume a range of enzyme mass from about 0.18-1.7 µg over 7 days of continuous operation. As Sternberg shows that it is desirable to consume less enzyme mass, it would have been obvious for one of ordinary skill in the art at the time the invention was made to configure the sensor of Kusano so that a range of enzyme mass from about 0.18-1.7 µg was consumed over 7 days of operation.

Claims 7, 8, 23, 27 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kusano in view of Rhodes.

In regard to claims 23, 27, 29 and 30, Kusano teaches an implantable body comprising an electrode configured to measure a glucose level in a host (see Fig. 3 and pages 2-3). Kusano teaches a membrane located over at least a portion of the electrode surface, the membrane comprising polyurethane and having a resistance domain configured to limit transport of glucose to the electrode, including an enzyme

configured to catalyze a reaction of glucose and oxygen (see Fig. 2 and pages 1-3). Kusano also teaches sensor electronics operably connected to the electrode. Kusano also teaches that the sensor system measures glucose concentrations from 0 to 500 mg/dL, in a fluid with an oxygen concentration ranging from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg) (see pages 6-7). Kusano also teaches that the electrode had a linear response to glucose concentration at an electrode output current ranging from 0 to 20nA even when the oxygen concentration of the glucose solution is zero (see Abstract and Fig. 8). Kusano also teaches that glucose concentrations of 0 to 500 mg/dL can be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (see page 8). Oxygen concentration had no effect on electrode response (see pages 6-7 and Fig 8). ***With further respect to claim 23 and in regard to claims 7, 8 and 31***, Kusano is silent as to the resistance domain having a permeability ratio of at least about 50:1 oxygen to glucose or 100:1 oxygen to glucose. However, Rhodes teaches implantable glucose sensors having multi-region membrane systems that include resistance domains having oxygen-to-glucose permeability ratios of approximately 200:1 (see pages 6-7). Rhodes teaches a sensor system configured to have a sensor output of at least 5.5 pA/mg/dL between 0-300 mg/dL (see Fig. 3). Since Rhodes teaches the desirability of resistance domains having a permeability of approximately 200:1, it would have been obvious for one of ordinary skill in the art at the time the invention was made to configure Kusano to have the resistance domain taught by Rhodes.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kusano in view of Sternberg and further in view of Rhodes.

In regard to claim 17, Kusano is silent as to the resistance domain having a permeability ratio of at least about 50:1 oxygen to glucose or 100:1 oxygen to glucose. However, Rhodes teaches implantable glucose sensors having multi-region membrane systems that include resistance domains having oxygen-to-glucose permeability ratios of approximately 200:1 (see pages 6-7). Rhodes teaches a sensor system configured to have a sensor output of at least 5.5 pA/mg/dL between 0-300 mg/dL (see Fig. 3). Since Rhodes teaches the desirability of resistance domains having a permeability of approximately 200:1, it would have been obvious for one of ordinary skill in the art at the time the invention was made to configure Kusano to have the resistance domain taught by Rhodes.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kusano in view of Rhodes and further in view of Sternberg.

In regard to claim 24, Kusano is silent as to less than about 1 μg of enzyme being consumed over 7 days of continuous operation. However, Sternberg teaches three procedures for preparing electrodes with immobilized glucose oxidase (GOx)and examines time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface (see page 2784 and Fig. 5). Fig. 5 shows that the relative consumption of GOx over the first seven days of use is between about 10% and about 15%, resulting in a consumption of about 0.18-0.63 μg (prepared with procedure a),

0.42-1.3 μg (prepared with procedure b) and 0.86-1.7 μg (prepared with procedure c). Sternberg thus teaches how to configure a system to consume a range of enzyme mass from about 0.18-1.7 μg over 7 days of continuous operation. As Sternberg shows that it is desirable to consume less enzyme mass, it would have been obvious for one of ordinary skill in the art at the time the invention was made to configure the sensor of Kusano so that a range of enzyme mass from about 0.18-1.7 μg was consumed over 7 days of operation.

Claims 1, 7, 8, 23 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhodes.

In regard to claims 1 and 23, Rhodes teaches a continuous glucose sensor system having an implantable body comprising an electrode configured to measure a glucose level in a host (see Abstract, page 2, paragraphs 0012-0017 and 0020). Rhodes also teaches a membrane disposed over the electrode that comprises a resistance domain configured to limit transport of glucose to the electrode (see page 5, paragraph 0062 to page 8, paragraph 0108 and Figs. 2A-2F). Rhodes also teaches an enzyme configured to catalyze a reaction of glucose and oxygen (see page 7, paragraphs 0086-0088). Rhodes also teaches sensor electronics operably connected to the electrode and that testing was conducted up to a glucose concentration of 400 mg/dL and that sensitivity of the sensor to glucose was given as the slope of sensor output versus glucose concentration (see page 10). Rhodes teaches recording glucose values at oxygen concentrations as low as approximately 0.1 mg/L (see page 10). ***In***

regard to claims 7, 8 and 31, Rhodes teaches oxygen-to-glucose permeability ratios of approximately 200:1 (see pages 6-7). ***With further respect to claim 23***, Rhodes teaches a sensor system configured to have a sensor output of at least 5.5 pA/mg/dL between 0-300 mg/dL (see Fig. 3).

Scope of Reexamination

Since requester did not request reexamination of claims 10, 11, 13, 19, 20, 22, 25, 26 and 28 and did not assert the existence of a substantial new question of patentability (SNQP) for such claims (see 35 U.S.C. § 311(b)(2); see also 37 CFR 1.915b and 1.923), such claims will not be reexamined. This matter was squarely addressed in *Sony Computer Entertainment America Inc., et al. v. Jon W. Dudas*, Civil Action No. 1:05CV1447 (E.D.Va. May 22, 2006), Slip Copy, 2006 WL 1472462. (Not Reported in F.Supp.2d.) The District Court upheld the Office's discretion to not reexamine claims in an *inter partes* reexamination proceeding other than those claims for which reexamination had specifically been requested. The Court stated:

> To be sure, a party may seek, and the PTO may grant, *inter partes* review of each and every claim of a patent. Moreover, while the PTO in its discretion may review claims for which *inter partes* review was not requested, nothing in the statute compels it to do so. To ensure that the PTO considers a claim for *inter partes* review, § 311(b)(2) requires that the party seeking reexamination demonstrate why the PTO should reexamine each and every claim for which it seeks review. Here, it is undisputed that Sony did not seek review of every claim under the '213 and '333 patents. Accordingly, Sony cannot now claim that the PTO wrongly failed to reexamine claims for which Sony never requested review, and its argument that AIPA compels a contrary result is unpersuasive.

(Slip copy at page 9.)

The *Sony* decision's reasoning and statutory interpretation apply analogously to *ex parte* reexamination, as the same relevant statutory language applies to both *inter partes* and *ex parte* reexamination. 35 U.S.C. § 302 provides that the *ex parte* reexamination "request must set forth the pertinency and manner of applying cited prior art to every claim for which reexamination is requested" (emphasis added), and 35 U.S.C. § 303 provides that "the Director will determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request..." (Emphasis added). These provisions are analogous to the language of 35 U.S.C. § 311(b)(2) and 35 U.S.C. § 312 applied and construed in *Sony*, and would be construed in the same manner. As the Director can decline to reexamine non-requested claims in an *inter partes* reexamination proceeding, the Director can likewise do so in *ex parte* reexamination proceeding. See *Notice of Clarification of Office Policy To Exercise Discretion in Reexamining Fewer Than All the Patent Claims* (signed Oct. 5, 2006) 1311 OG 197 (Oct. 31, 2006). See also MPEP § 2240, Rev. 5, Aug. 2006.

Therefore, claims 10, 11, 13, 19, 20, 22, 25, 26 and 28 will not be reexamined in this ex *partes* reexamination proceeding.

Conclusion

Please mail any communications to:

Attn: Mail Stop "Ex Parte Reexam"
Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Please FAX any communications to:

(571) 273-9900
Central Reexamination Unit

Please hand-deliver any communications to:

Customer Service Window
Attn: Central Reexamination Unit
Randolph Building, Lobby Level
401 Dulaney Street
Alexandria, VA 22314

Any inquiry concerning this communication or earlier communications from the Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:

/Beverly M. Flanagan/

Beverly M. Flanagan
CRU Examiner
GAU 3993
(571) 272-4766

Conferee /JRJ/

Conferee ____

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/011,468	02/01/2011	771352	ADCI-GEN51	9182

20995 7590 02/17/2011

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
ART UNIT	**PAPER NUMBER**

DATE MAILED: 02/17/2011

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

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THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS
ABBOTT DIABETES CARE INC.
BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVE., SUITE 200
EAST PALO ALTO, CA 94303

Date: MAILED

FEB 17 2011

CENTRAL REEXAMINATION UNIT

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. : 90011468
PATENT NO. : 7771352
ART UNIT : 3993

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified ex parte reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the ex parte reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Ex Parte Reexamination Interview Summary – Pilot Program for Waiver of Patent Owner's Statement	Control No. 90/011,468	Patent For Which Reexamination is Requested 7,771,352
	Examiner	Art Unit 3993

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

All participants (USPTO official and patent owner):

(1) Patricia Martin, CRU (3)

(2) Rose Thiessen, 40202 (4)

Date of Telephonic Interview: 02/16/11.

The USPTO official requested waiver of the patent owner's statement pursuant to the pilot program for waiver of patent owner's statement in *ex parte* reexamination proceedings.*

☒ The patent owner **agreed** to waive its right to file a patent owner's statement under 35 U.S.C. 304 in the event reexamination is ordered for the above-identified patent.

☐ The patent owner **did not agree** to waive its right to file a patent owner's statement under 35 U.S.C. 304 at this time.

The patent owner is <u>not</u> required to file a written statement of this telephone communication under 37 CFR 1.560(b) or otherwise. However, any disagreement as to this interview summary must be brought to the immediate attention of the USPTO, and no later than one month from the mailing date of this interview summary. Extensions of time are governed by 37 CFR 1.550(c).

*For more information regarding this pilot program, see *Pilot Program for Waiver of Patent Owner's Statement in Ex Parte Reexamination Proceedings*, 75 *Fed. Reg.* 47269 (August 5, 2010), available on the USPTO Web site at http://www.uspto.gov/patents/law/notices/2010.jsp.

☐ USPTO personnel were unable to reach the patent owner.

The patent owner may contact the USPTO personnel at the telephone number provided below if the patent owner decides to waive the right to file a patent owner's statement under 35 U.S.C. 304.

/Patricia Martin/ 571-272-5004

Signature and telephone number of the USPTO official who contacted or attempted to contact the patent owner.

cc: Requester (if third party requester)

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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P.O. Box 1450
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REEXAM CONTROL NUMBER	FILING OR 371 (c) DATE	PATENT NUMBER
90/011,468	02/01/2011	7771352

CONFIRMATION NO. 9182

REEXAMINATION REQUEST NOTICE

ABBOTT DIABETES CARE INC.
BOZICEVIC, FIELD & FRANCIS, LLP
1900 UNIVERSITY AVENUE, SUITE 200
EAST PALO ALTO, CA 94303

OC000000045975252

Date Mailed: 02/14/2011

NOTICE OF REEXAMINATION REQUEST FILING DATE

(Third Party Requester)

Requester is hereby notified that the filing date of the request for reexamination is 02/01/2011, the date that the filing requirements of 37 CFR § 1.510 were received.

A decision on the request for reexamination will be mailed within three months from the filing date of the request for reexamination. (See 37 CFR 1.515(a)).

A copy of the Notice is being sent to the person identified by the requester as the patent owner. Further patent owner correspondence will be the latest attorney or agent of record in the patent file. (See 37 CFR 1.33). Any paper filed should include a reference to the present request for reexamination (by Reexamination Control Number).

cc: Patent Owner
20995
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
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IRVINE, CA 92614

/rbell/

Legal Instruments Examiner
Central Reexamination Unit 571-272-7705; FAX No. 571-273-9900

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REEXAM CONTROL NUMBER	FILING OR 371 (c) DATE	PATENT NUMBER
90/011,468	02/01/2011	7771352

CONFIRMATION NO. 9182

REEXAM ASSIGNMENT NOTICE

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

OC000000045975253

Date Mailed: 02/14/2011

NOTICE OF ASSIGNMENT OF REEXAMINATION REQUEST

The above-identified request for reexamination has been assigned to Art Unit 3993. All future correspondence to the proceeding should be identified by the control number listed above and directed to the assigned Art Unit.

A copy of this Notice is being sent to the latest attorney or agent of record in the patent file or to all owners of record. (See 37 CFR 1.33(c)). If the addressee is not, or does not represent, the current owner, he or she is required to forward all communications regarding this proceeding to the current owner(s). An attorney or agent receiving this communication who does not represent the current owner(s) may wish to seek to withdraw pursuant to 37 CFR 1.36 in order to avoid receiving future communications. If the address of the current owner(s) is unknown, this communication should be returned within the request to withdraw pursuant to Section 1.36.

cc: Third Party Requester(if any)
ABBOTT DIABETES CARE INC.
BOZICEVIC, FIELD & FRANCIS, LLP
1900 UNIVERSITY AVENUE, SUITE 200
EAST PALO ALTO, CA 94303

/rbell/

Legal Instruments Examiner
Central Reexamination Unit 571-272-7705; FAX No. 571-273-9900

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/011,468		771352	ADCI-GEN51	9182

20995 7590 02/11/2011

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
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EXAMINER

ART UNIT	PAPER NUMBER

DATE MAILED: 02/11/2011

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THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS
ABBOTT DIABETES CARE INC.
BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVE., SUITE 200
EAST PALO ALTO, CA 94303

Date:

MAILED

FEB 11 2011

CENTRAL REEXAMINATION UNIT

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. : 90011468
PATENT NO. : 7771352
ART UNIT : 3993

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified ex parte reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the ex parte reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Ex Parte Reexamination Interview Summary – Pilot Program for Waiver of Patent Owner's Statement	**Control No.** 90/011,468	**Patent For Which Reexamination is Requested** 7,771,352
	Examiner	**Art Unit** 3993

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

All participants (USPTO official and patent owner):

(1) Patricia Martin, CRU (3)

(2) Rose Thiessen, 40202 (4)

Date of Telephonic Interview: 2/9/11.

The USPTO official requested waiver of the patent owner's statement pursuant to the pilot program for waiver of patent owner's statement in *ex parte* reexamination proceedings.*

☐ The patent owner **agreed** to waive its right to file a patent owner's statement under 35 U.S.C. 304 in the event reexamination is ordered for the above-identified patent.

☐ The patent owner **did not agree** to waive its right to file a patent owner's statement under 35 U.S.C. 304 at this time.

The patent owner is not required to file a written statement of this telephone communication under 37 CFR 1.560(b) or otherwise. However, any disagreement as to this interview summary must be brought to the immediate attention of the USPTO, and no later than one month from the mailing date of this interview summary. Extensions of time are governed by 37 CFR 1.550(c).

*For more information regarding this pilot program, see *Pilot Program for Waiver of Patent Owner's Statement in Ex Parte Reexamination Proceedings*, 75 *Fed. Reg.* 47269 (August 5, 2010), available on the USPTO Web site at http://www.uspto.gov/patents/law/notices/2010.jsp.

☒ USPTO personnel were unable to reach the patent owner.

The patent owner may contact the USPTO personnel at the telephone number provided below if the patent owner decides to waive the right to file a patent owner's statement under 35 U.S.C. 304.

/Patricia Martin/
Paralegal Specialist 571-272-5004
Signature and telephone number of the USPTO official who contacted or attempted to contact the patent owner.

cc: Requester (if third party requester)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Shults et al.	Attorney Docket No. ADCI-GEN51
U.S. Patent No.: 7,771,352 (*issued from Appl. No. 12/113,508*)	Group Art Unit: *Not yet assigned*
Issued: August 10, 2010	Confirmation No. *Not yet assigned*
For: Low Oxygen In Vivo Analyte Sensor	Examiner: *Not yet assigned*
	Reexamination Control No.: *Not yet assigned*

ABBOTT DIABETES CARE INC.'S REQUEST FOR *EX PARTE* REEXAMINATION OF U.S. PATENT NO. 7,771,352 UNDER 35 U.S.C. § 302 AND 37 C.F.R. § 1.510

Mail Stop *Ex Parte* Reexam
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Abbott Diabetes Care Inc. (hereinafter "Requestor") requests reexamination under 35 U.S.C. § 302 and 37 C.F.R. § 1.510 of U.S. Patent No. 7,771,352, which issued on August 10, 2010, to Shults et al. (hereinafter "the Shults '352 patent").

As is fully explained and supported below, a substantial new question of patentability of claims 1-9, 12, 14-18, 21, 23, 24, 27, and 29-31of the Shults '352 patent is raised by prior art teachings that were not considered or applied by the examiner during the original prosecution of the Shults '352 patent. More specifically, as outlined in Section V, a substantial new question of patentability is raised by teachings in each of the Kusano publication, the Sternberg publication, and the Rhodes '874 publication. For example, the Kusano publication teaches the alleged patentable features of claims 1-9, 12, 15, and 29. The Sternberg publication teaches the alleged patentable features of claims 2, 14-18, 21, and 24. The Rhodes '874 publication teaches the alleged patentable features of claims 1-9, 12, 23, 24, 27, and 29-31. As such, a reasonable examiner would have considered the teachings of the Kusano publication, the Sternberg

publication, and the Rhodes '874 publication to be important in deciding whether the recited claims are patentable.

Pursuant to 37 C.F.R. § 1.510, included with this request for *ex parte* reexamination are the following:

- a citation of the printed publications that are presented to provide substantial new questions of patentability (37 C.F.R. § 1.501);
- the fee for requesting *ex parte* reexamination as set forth in 37 C.F.R. § 1.20(c)(1) (paid via EFS Fee Payment Screen) (37 C.F.R. § 1.510(a));
- a statement pointing out each substantial new question of patentability based on the cited printed publications (37 C.F.R. § 1.510(b)(1));
- an identification of every claim for which reexamination is requested, and a detailed explanation of the manner and pertinence of applying the printed publications to every claim for which reexamination is requested (37 C.F.R. § 1.510(b)(2));
- a copy of each patent and printed publication relied upon or referred to in this request (37 C.F.R. § 1.510(b)(3));
- a copy of the entire patent (in double column format) for which reexamination is requested, and a copy of any disclaimer, certificate of correction, or reexamination certificate issued in the patent (37 C.F.R. § 1.510(b)(4));
- a certification that this request has been served in its entirety on the patent owner through the attorney of record during prosecution (37 C.F.R. § 1.510(b)(5)); and
- a statement that the attorney filing this request has the authority to act on behalf of the Requestor pursuant to 37 C.F.R. § 1.34 (37 C.F.R. § 1.510(f)).

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I. IDENTIFICATION OF CLAIMS FOR WHICH REEXAMINATION IS REQUESTED (37 C.F.R. § 1.510(b)(2))

Ex parte reexamination is requested of claims 1-9, 12, 14-18, 21, 23, 24, 27, and 29-31 of the Shults '352 patent. Claims 1-9, 12, 14-18, 21, 23, 24, 27, and 29-31 of the Shults '352 patent are hereinafter referred to individually and/or collectively as "the claims for which reexamination is requested." In accordance with 37 C.F.R. § 1.510(b)(4), a copy of the Shults '352 patent is attached as **Exhibit A**.

II. CITATION OF PRIOR ART (37 C.F.R. § 1.501)

Reexamination is requested in view of the following documents, which are listed on the accompanying Form PTO/SB/08A. In accordance with 37 C.F.R. § 1.510(b)(3), a copy of each of the following references is attached.

Exhibit	Prior Art Document	Previously Cited?	Applied By The Examiner During Prosecution?
B	Kerner, *et al.*, A Potentially Implantable Enzyme Electrode for Amperometric Measurement of Glucose, *Horm Metab Res Suppl.*, 20:8-13 (1989) (herein referred to as "the Kerner publication").	**Yes**	**Yes**
C	Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissolved oxygen, *Clin. Phys. Physiol. Meas.*, vol. 10, 1:1-9 (1989) (herein referred to as "the Kusano publication").	**No**	**No**
D	Sternberg, *et al.*, Covalent Enzyme Coupling on Cellulose Acetate Membranes for Glucose Sensor Development, *Anal. Chem.*, 60: 2781-2786 (1988) (herein referred to as "the Sternberg publication").	**No**	**No**
E	U.S. Patent Publication No. 2003/0032874 (herein referred to as "the Rhodes '874 publication").	**Yes**	**No**

The Kerner publication published in 1988, which is more than one year before the effective filing date of the Shults '352 patent. As such, the Kerner publication qualifies as prior art under 35 U.S.C. § 102(b). A detailed explanation of the pertinence and manner of applying the Kerner publication to the claims for which reexamination is requested is provided below.

The Kusano publication published in 1989, which is more than one year before the effective filing date of the Shults '352 patent. As such, the Kusano publication qualifies as prior art under 35 U.S.C. § 102(b). A detailed explanation of how the Kusano publication presents a substantial new question of patentability, and the manner and pertinence of applying the Kusano publication to the claims for which reexamination is requested, is provided below.

The Sternberg publication published in 1988, which is more than one year before the effective filing date of the Shults '352 patent. As such, the Sternberg publication qualifies as prior art under 35 U.S.C. § 102(b). A detailed explanation of how the Sternberg publication presents a substantial new question of patentability, and the manner and pertinence of applying the Sternberg publication to the claims for which reexamination is requested, is provided below.

The Rhodes '874 publication published on February 13, 2003, which is more than one year before the effective filing date of the Shults '352 patent. As such, the Rhodes '874 publication qualifies as prior art under 35 U.S.C. § 102(b). A detailed explanation of how the Rhodes '874 publication presents a substantial new question of patentability, and the manner and pertinence of applying the Rhodes '874 publication to the claims for which reexamination is requested, is provided below.

III. OVERVIEW OF APPLICABLE PATENT LAW

A. Substantial New Question of Patentability

In determining whether a substantial new question of patentability (SNQ) exists, M.P.E.P. § 2242, Subtitle I, paragraph 3, provides:

> A prior art patent or printed publication raises a substantial new question of patentability where there is a substantial likelihood that a reasonable examiner would consider the prior art or printed publication important in deciding whether or not the claim is patentable.

The Federal Circuit has held that "the existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office." *In re Swanson*, 540 F.3d 1368,1379-1380 (Fed. Cir. 2008). Thus, "a reference may present a substantial new question even if the examiner considered or cited a reference for one purpose in earlier proceedings." *Id.* The M.P.E.P. is consistent with the *Swanson* decision. M.P.E.P. § 2258.01(A) provides that "[f]or a reexamination that was ordered on or after November 2, 2002 ... reliance solely on old art (as the basis for a rejection) does not necessarily preclude the existence of a substantial new question of patentability that is based exclusively on that old art." Thus, "a SNQ may be based solely on old art where the old art is being presented/viewed in a new light, or in a different way, as compared with its use in the earlier concluded examination(s)." *Id.*

B. Broadest Reasonable Construction

For purposes of this reexamination request, each term of the claims is to be given its "broadest reasonable construction" consistent with the specification. M.P.E.P. § 2111; *In re Trans Texas Holding Corp.*, 498 F.3d 1290, 1298 (Fed. Cir. 2007). As the Federal Circuit noted in *Trans Texas*, the USPTO has traditionally applied this standard during reexamination and does not interpret claims as a court would interpret claims. Rather:

> [T]he PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification.

In re Morris, 127 F.3d 1048, 1054-55 (Fed. Cir. 1997).

The rationale underlying the "broadest reasonable construction" standard is that it reduces the possibility that a claim, after issuance or certificate of reexamination, will be interpreted more broadly than is justified. 37 C.F.R. § 1.555(b); M.P.E.P. § 2111.

C. Overview of Anticipation

A patent is unpatentable under 35 U.S.C. § 102 if it is anticipated by a prior art reference. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). A feature may be inherent if "the prior art necessarily functions in accordance with, or includes, the limitations." *Telemac Cellular Corp. v. Top Telecom, Inc.*, 247 F.3d 1316, 1328 (Fed. Cir. 2001). While normally only one reference should be used in making a rejection under 35 U.S.C. § 102, multiple references may be used when an extra reference is cited to show that a characteristic, which may not be disclosed in the main reference, is inherent. M.P.E.P. § 2131.01. The critical date of the extra reference, which is being used solely to show a universal fact, need not antedate the filing date of the application in question. *Id.*

D. Overview of Obviousness

Section 103 forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). In making an obviousness determination, "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions." *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007). In *KSR*, the Supreme Court rejected the "rigid approach" of the former "teaching-suggestion-motivation to combine" or "TSM" test. *Id.* at 1739. At the same time, the Court reaffirmed the principles of obviousness set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). *Id.* at 1734.

The obviousness analysis involves the comparison of the broadly construed claim to the prior art. In comparing the claim to the prior art, three factual inquiries must be addressed: (1)

the scope and content of the prior art must be ascertained; (2) the differences between the claimed invention and the prior art must be determined; and (3) the level of ordinary skill in the pertinent art at the time the invention was made must be evaluated. *Graham*, 383 U.S. at 17-18. As stated by the Supreme Court in *KSR*, "[w]hile the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls." *KSR*, 127 S.Ct. at 1734.

In view of the Supreme Court's decision in *KSR*, the Office issued "Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*" See 72 Fed. Reg. 57,526 (Oct. 10, 2007) (hereinafter "Examination Guidelines"). According to the Examination Guidelines, "the Supreme Court particularly emphasized 'the need for caution in granting a patent based on the combination of elements found in the prior art.'" 72 Fed. Reg. at 57,526 (citing to *KSR*). The guidelines further state that "the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge." 72 Fed. Reg. at 57,527. According to the Supreme Court, the "person of ordinary skill" should be viewed as "a person of ordinary creativity, not an automaton." *KSR*, 127 S.Ct. at 1742. The Supreme Court further stated that "in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id.*

Further, "[w]here a claimed range overlaps with a range disclosed in the prior art, there is a presumption of obviousness." *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006) (citations omitted); see also M.P.E.P. § 2144.05.

IV. OVERVIEW OF THE SHULTS '352 PATENT

A. The Shults '352 patent

The Shults '352 patent issued on August 10, 2010, from U.S. Patent Application No. 12/113,508 ("the Shults '508 application"). The Shults '508 application was filed on May 1, 2008, and claims priority as a continuation application to U.S. Application Ser. No. 11/333,837, filed Jan. 17, 2006; which is a continuation-in-part of U.S. Application Ser. No. 11/077,714, filed Mar. 10, 2005; which claims priority under 35 U.S.C. 119(e) to U.S. Provisional Application No. 60/614,683, filed Sep. 30, 2004; U.S. Provisional Application No. 60/614,764, filed Sep. 30, 2004; U.S. Provisional Application No. 60/587,787, filed Jul. 13, 2004; and U.S. Provisional Application No. 60/587,800, filed Jul. 13, 2004.

The Shults '352 patent relates to devices for measuring glucose levels in a host. See the Shults '352 patent, col. 1, lns. 20-24. More specifically, the Shults '352 patent claims a continuous glucose sensor system having an implantable electrode and a membrane disposed over the electrode. See, for example, claims 1-31; and col. 1, ln. 58 – col. 2, ln. 3. The membrane is configured to limit transport of glucose to the electrode. *Id.* The system also includes an enzyme to catalyze a reaction of glucose and oxygen. *Id.*

Most relevant to this reexamination request, the system claimed in the Shults '352 patent includes sensor electronics that are "configured to measure glucose concentration with substantial linearity at glucose concentrations up to about 400 mg/dL at an oxygen concentration of less than about 0.3 mg/L." See claims 1-13, 15, and 29. Additionally, the system claimed in the Shults '352 patent is configured to have, in operation, "a sensitivity of from about 5pA/mg/dL to about 25 pA/mg/dL." See claims 23-31. Further, the system is "configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation." See claims 14-22, and 24. As will be outlined below, the alleged linearity, sensitivity, and consumption of the system claimed in the Shults '352 patent played an important role in the examiner's decision to allow the claims for which reexamination is requested.

B. Issued Claims of the Shults '352 patent

The Shults '352 patent issued with three independent claims, and 31 total claims. The claims for which reexamination is requested are reproduced below.

1. A continuous glucose sensor system comprising:
an implantable body comprising an electrode configured to measure a glucose level in a host;
a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme configured to catalyze a reaction of glucose and oxygen; and
sensor electronics operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L.

2. The continuous glucose sensor system of claim 1, wherein the system is configured such that less than about 1μg of enzyme is consumed over 7 days of continuous operation.

3. The continuous glucose sensor system of claim 1, wherein the oxygen concentration is less than about 0.15 mg/L.

4. The continuous glucose sensor system of claim 1, wherein the oxygen concentration of is less than about 0.05 mg/L.

5. The continuous glucose sensor system of claim 1, wherein the oxygen concentration of is less than about 0.02 mg/L.

6. The continuous glucose sensor system of claim 1, wherein the electrode comprises an exposed electroactive working electrode surface with a surface area of from about 0.00002 in^2 to about 0.0079 in^2.

7. The continuous glucose sensor system of claim 1, wherein the resistance domain is configured to have a permeability ratio of at least about 50:1 of oxygen to glucose.

8. The continuous glucose sensor system of claim 7, wherein the resistance domain is configured to have a permeability ratio of at least about 200:1 of oxygen to glucose.

9. The continuous glucose sensor system of claim 1, wherein the sensor system is configured to have, in operation, a sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL.

12. The continuous glucose sensor system of claim 1, wherein the resistance domain comprises a polyurethane.

14. A continuous glucose sensor system comprising:
an implantable body comprising an electrode configured to measure a glucose level in a host;
a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme configured to catalyze a reaction of glucose and oxygen; and
a sensor electronics unit operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L, wherein the system is configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation.

15. The continuous glucose sensor system of claim 14, wherein the oxygen concentration is less than about 0.3 mg/L.

16. The continuous glucose sensor system of claim 14, wherein the electrode comprises an exposed electroactive working electrode surface with a surface area of from about 0.00002 in^2 to about 0.0079 in^2.

17. The continuous glucose sensor system of claim 14, wherein the resistance domain is configured to have a permeability ratio of at least about 50:1 of oxygen to glucose.

18. The continuous glucose sensor system of claim 14, wherein the sensor system is configured to have, in operation, a sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL.

21. The continuous glucose sensor system of claim 14, wherein the resistance domain comprises a polyurethane.

23. A continuous glucose sensor system comprising:
an implantable body comprising an electrode configured to measure a glucose level in a host;
a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme configured to catalyze a reaction of glucose and oxygen; and
a sensor electronics unit operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less

than about 0.6 mg/L, wherein the sensor system is configured to have, in operation, a sensitivity of from about 5 pA/mg/dL to about 25 pA/mg/dL.

24. The continuous glucose sensor system of claim 23, wherein the system is configured such that less than about 1μg of enzyme is consumed over 10 days of continuous operation.

27. The continuous glucose sensor system of claim 23, wherein the resistance domain comprises a polyurethane.

29. The continuous glucose sensor system of claim 23, wherein the oxygen concentration is less than about 0.3 mg/L.

30. The continuous glucose sensor system of claim 23, wherein the electrode comprises an exposed electroactive working electrode surface with a surface area of from about 0.00002 in^2 to about 0.0079 in^2.

31. The continuous glucose sensor system of claim 23, wherein the resistance domain is configured to have a permeability ratio of at least about 50:1 of oxygen to glucose.

C. Relevant Prosecution History of the Shults '352 patent

The Shults '508 application was filed with 15 original claims. Claims 1 and 12 were the independent claims. On October 30, 2009, in response to a Restriction Requirement, applicants cancelled claims 12-15. As such, original application claims 1-11 remained pending for examination, and claim 1 was the only independent claim. Relevant to this reexamination request, original application claims 1, 2, 10, and 11 are reproduced below.

1. A continuous glucose sensor system comprising:

an implantable body comprising an electrode configured to measure a glucose level in a host;

a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme to catalyze a reaction of glucose and oxygen as a co-reactant; and

a sensor electronics unit operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L.

> 2. The continuous glucose sensor system of Claim 1, wherein the sensor electronics unit is configured to measure glucose in a fluid with an oxygen concentration of less than about 0.3 mg/L.
>
> 10. The continuous glucose sensor system of Claim 1, wherein the sensor system is configured to have, in operation, a sensitivity of from about 5 pA/mg/dL to about 25 pA/mg/dL.
>
> 11. The continuous glucose sensor system of Claim 1, wherein the system is configured such that less than about 1μg of enzyme is consumed over 7 days of continuous operation.

On February 23, 2010 the examiner issued a first office action on the merits. In relevant part, claims 1, 6, and 9 were rejected under 35 U.S.C. § 102(b) as being anticipated by the Kerner publication. The examiner determined that the Kerner publication taught each and every feature of claims 1, 6, and 9. Specifically, the examiner held:

> Regarding claim 1, Kerner teaches a continuous glucose sensor system comprising an implantable body comprising an electrode configured to measure a glucose level in a host, a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme to catalyze a reaction of glucose and oxygen as a co-reactant, and sensor electronics operably connected to the electrode (see entire document, especially the summary, "Construction of the glucose sensor" on p. 9, fig. 1 of Kerner). The electronics unit is configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L (see entire document, especially the summary, figs. 4 and 5, left hand column on p. 11 of Kerner), wherein oxygen concentrations above 0.5 mg/L include concentrations of less than about 0.6 mg/L.
>
> Regarding claim 6, the electrode comprises an exposed electroactive working electrode surface with a surface area between about 0.00002 in^2 and about 0.0079 in^2 (see entire document, especially "Construction of the glucose sensor" on p. 9 of Kerner), wherein the diameter of the working electrode is 0.3 mm (0.0118 in; surface area of about 0.0001 in^2).
>
> Regarding claim 9, the sensor system is configured to have, in operation, a sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL (see entire document, especially fig. 4; p. 11 of Kerner).

Office Action, dated Feb. 23, 2010, pgs. 3-4.

Claims 2-5, 10, and 11, however, were objected to as being dependent upon a rejected base claim. The examiner indicated, however, that claims 2-5, 10, and 11 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

With respect to claim 2, the examiner stated the reasons for allowance:

> the primary reason for allowance is the inclusion of the sensor electronics unit being configured to measure glucose in a fluid with an oxygen concentration of less than about 0.3 mg/L, … in combination with all of the other limitations of the claims, which is not taught or fairly suggested by the prior art of record.

Office Action, dated Feb. 23, 2010, pg. 6.

With respect to claim 10, the examiner stated that "the primary reason for allowance is the inclusion of the sensor system being configured to have, in operation, a sensitivity of from about 5 pA/mg/dL to about 25 pA/mg/dL, in combination with all of the other limitations of the claims, which is not taught or fairly suggested by the prior art of record." *Id.*

With respect to claim 11, the examiner stated that "the primary reason for allowance is the inclusion of the sensor system being configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation, in combination with all of the other limitations of the claims, which is not taught or fairly suggested by the prior art of record." *Id.*

On February 26, 2010, the applicants cancelled application claim 1, amended application claims 2-11, and added new claims 16-36. Relevant to this reexamination request, application claims 2, 10, and 11 were amended as follows:

> 2. <u>A continuous glucose sensor system comprising:</u>
>
> <u>an implantable body comprising an electrode configured to measure a glucose level in a host;</u>
>
> <u>a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme configured to catalyze a reaction of glucose and oxygen; and</u>
>
> <u>sensor electronics operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400</u>

mg/dL in a fluid with an oxygen concentration of less than about ~~The continuous glucose sensor system of Claim 1, wherein the sensor electronics unit is configured to measure glucose in a fluid with an oxygen concentration of less than about~~ 0.3 mg/L.

10. A continuous glucose sensor system comprising:

an implantable body comprising an electrode configured to measure a glucose level in a host;

a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme to catalyze a reaction of glucose and oxygen; and

a sensor electronics unit operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L ~~The continuous glucose sensor system of Claim 1~~, wherein the sensor system is configured to have, in operation, a sensitivity of from about 5 pA/mg/dL to about 25 pA/mg/dL.

11. A continuous glucose sensor system comprising:

an implantable body comprising an electrode configured to measure a glucose level in a host;

a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme configured to catalyze a reaction of glucose and oxygen; and

a sensor electronics unit operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L ~~The continuous glucose sensor system of Claim 1~~, wherein the system is configured such that less than about 1μg of enzyme is consumed over 7 days of continuous operation.

As such, applicants placed application claims 2, 10, and 11 in condition for allowance by rewriting the claims in independent form, in accordance with the examiner's suggestion in the February 23, 2010, office action.

On June 1, 2010, the examiner issued a Notice of Allowance. The examiner did not provide any additional reasons for allowance.

On August 10, 2010, the Shults '508 application issued as the Shults '352 patent. Application claim 2 was renumbered and issued as patent claim 1. Application claim 10 was renumbered and issued as patent claim 23. Application claim 11 was renumbered and issued as patent claim 14.

V. STATEMENT POINTING OUT EACH SUBSTANTIAL NEW QUESTION OF PATENTABILITY (37 C.F.R. § 1.510(b)(1))

A. The Kusano publication raises an SNQ because the Kusano publication teaches a sensor system that measures glucose in a fluid with an oxygen concentration of less than about 0.3 mg/L.

The Kusano publication was not cited during prosecution of the Shults '352 patent. Further, the examiner did not identify or apply any prior art that taught a sensor system with the features taught in the Kusano publication. The Kusano publication teaches a sensor system that measures glucose in a fluid with an oxygen concentration of less than about 0.3 mg/L, as called for in claims 1-9, 12, 15, and 29 of the Shults '352 patent. There is no indication that the examiner found, considered, or applied any prior art reference that taught such limitation. In fact, the examiner explicitly stated that claim 1 (application claim 2) was allowable because the examiner did not find art having sensor electronics configured to measure glucose in a fluid with an oxygen concentration of less than about 0.3 mg/L. As such, a reasonable examiner would consider the teachings of the Kusano publication important in deciding whether the claims for which reexamination is requested are patentable.

The Kusano publication is directed to the same problem as the Shults '352 patent; e.g., the development of an implantable sensor system for subcutaneous glucose concentration measurements in low oxygen environments. See, for example, the Kusano publication, pg. 2. The Kusano publication states, "The glucose electrode with percutaneous interface described in this paper differs from [previously described electrodes] using a novel approach to overcome the lack of oxygen in the interstitial fluid." *Id.* In other words, the Kusano publication presents a sensor system that address the oxygen deficiency problem, and thus measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.3 mg/L.

Specifically, the Kusano publication states,

> The electrode has a linear response to glucose concentration at an electrode output current ranging from 0 to 20nA ***even when the oxygen concentration of the glucose solution is zero***. The use of polyurethane as a diffusion barrier to glucose limits the electrode output current at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) to 20 nA. Therefore, the electrode can measure glucose concentrations up to 500 mg dl^{-1} (27.8 mmol l^{-1}) ***with no oxygen*** dissolved in the glucose solution.

The Kusano publication, Abstract (emphasis added).

Figure 8 of the Kusano publication (reproduced below) shows a linear current measurement up to 500 mg/dL, even at 0 kPa of Po_2.

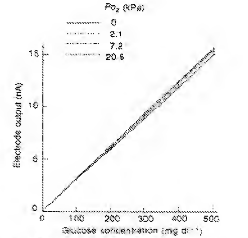


Figure 8. Electrode calibration curves under various Po_2

The concluding remarks of the Kusano publication further state:

> Glucose concentrations of 0 to 500 mg dl^{-1} (27.8 mmol l^{-1}) could be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (21.7 kPa). Since the electrode is capable of operating where the oxygen concentration is low, it is thought to be suitable for implantation in subcutaneous tissue and may prove to be a key development in the realisation of a closed-loop artificial endocrine pancreas.

The Kusano publication, pg. 8.

There is no indication that the examiner applied any prior art references that taught a sensor system that measures glucose in a fluid with an oxygen concentration of less than about 0.3 mg/L, as called for in claims 1-9, 12, 15, and 29 of the Shults '352 patent. As outlined above, such limitation is taught by the Kusano publication. As such, the Kusano publication alone, or in combination with the Kerner publication, raises a substantial new question of patentability because a reasonable examiner would consider the teachings of the Kusano publication important in deciding whether claims 1-9, 12, 15, and 29 are patentable. See M.P.E.P. § 2242, Subtitle I, paragraph 3.

A detailed explanation of the pertinence and manner of applying the teachings of the Kusano publication to claims 1-9, 12, 15, and 29 is provided below in Section VI.

B. The Sternberg publication raises an SNQ because the Sternberg publication teaches a sensor system that is configured to consume less than 1μg of enzyme over 7 days of continuous operation.

The Sternberg publication was not cited during prosecution of the Shults '352 patent. Further, the examiner did not identify or apply any prior art that taught a sensor system with the features taught in the Sternberg publication. The Sternberg publication teaches a sensor system that is configured to consume less than 1 μg of enzyme over 7 days of continuous operation. There is no indication that the examiner found, considered, or applied any prior art reference that taught such feature. In fact, the examiner explicitly stated that claim 14 (application claim 11) was allowable because the examiner did not find art that includes a sensor system "configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation." Because the Sternberg publication teaches a sensor system that consumes less than 1 μg of enzyme over 7 days of continuous operation, a reasonable examiner would consider the teachings of the Sternberg publication important in deciding whether claims 2, 14-18, 21, and 24 are patentable.

The Sternberg publication is directed to the same problem as the Shults '352 patent, which is the development of an implantable sensor system for subcutaneous glucose concentration measurements. See, for example, the Sternberg publication, pg. 2783, Results and Discussion section. The Sternberg publication describes experiments with electrodes containing 3.0 ± 1.2 μg, 6.4 ± 2.2 μg, and 10 ± 1.4 μg of immobilized glucose oxidase (GOx), respectively. *Id.* at pg. 2782-83, Table I (procedure "a" provides 3.8 ± 1.5 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 3.0 ± 1.2 μg of enzyme; procedure "b" provides 8.0 ± 2.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 6.4 ± 2.2 μg of enzyme; and procedure "c" provides 13 ± 1.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 10 ± 1.4 μg of enzyme).

As discussed on page 2784 of the Sternberg publication, "Figure 5 compares the time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface." The line noted with the "X" markers in Figure 5 (reproduced below) illustrates the consumption of GOx over about 15 days of continuous use. As shown in Figure 5, the relative consumption of GOx over the first seven days of use is between about 10% and about 15%.

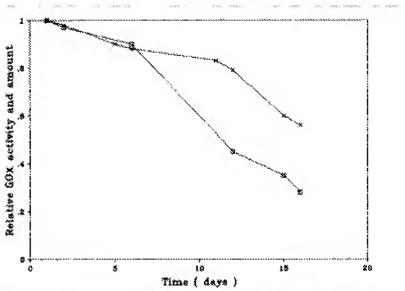


Figure 5. Relative evolution of surface GOx activity (O) and ^{125}I–GOx (X) in a CA–BSA–PBQ–GOx membrane not treated with lysine after coupling.

Considering preparation procedures "a," "b," and "c," which begin with 3.0 ± 1.2 μg; 6.4 ± 2.2 μg; and 10 ± 1.4 μg, respectively, a 10-15% consumption of enzyme would result in consumption of about 0.18-0.63 μg; 0.42-1.3 μg; or 0.86-1.7 μg, respectively. As such, the Sternberg publication teaches a system that is configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation.

The Sternberg publication raises a substantial new question of patentability because it teaches a continuous glucose measurement sensor consuming less than 1 μg over 7 days of continuous operation. A reasonable examiner would consider such teachings important in deciding whether claims 2, 14-18, 21, and 24 are patentable. See M.P.E.P. § 2242, Subtitle I, paragraph 3.

A detailed explanation of the pertinence and manner of applying the teachings of the Sternberg publication to claims 2, 14-18, 21, and 24 is provided below in Section VI.

C. The Rhodes '874 publication raises an SNQ because the Rhodes '874 publication teaches a sensor system that measures glucose in a fluid with an oxygen concentration of less than about 0.3 mg/L.

The Rhodes '874 publication was cited during prosecution of the Shults '352 patent, but the teachings of the Rhodes '874 publication were not applied against the claims of the Shults '352 patent. The Rhodes '874 publication teaches a sensor system that measures glucose in a

fluid with an oxygen concentration of less than about 0.3 mg/L, as called for in claims 1-9, 12, 15, and 29 of the Shults '352 patent. There is no indication that the examiner found, considered, or applied any prior art reference that taught such limitation. In fact, the examiner explicitly stated that claim 1 (application claim 2) was allowable because the examiner did not find art having sensor electronics configured to measure glucose in a fluid with an oxygen concentration of less than about 0.3 mg/L. As such, a reasonable examiner would consider the teachings of the Rhodes '874 publication important in deciding whether the claims for which reexamination is requested are patentable.

The Rhodes '874 publication is directed to the same problem as the Shults '352 patent; e.g., the development of an implantable sensor system for subcutaneous glucose concentration measurements in low oxygen environments. See the Rhodes '874 publication, pg. 1, [0003]; and pg. 2, [0011]. The Rhodes '874 publication states, "there is a need for a sensor that will provide accurate analyte measurements, ... and that will function effectively and efficiently in low oxygen concentration environments." Pg. 2, [0011].

The Rhodes '874 publication presents a sensor system that address the oxygen deficiency problem and measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.3 mg/L. Specifically, in EXAMPLE 2, on page 10, the Rhodes '874 publication states, "A glucose value was recorded for each device at decreasing oxygen concentrations from ambient to approximately 0.1 mg/L." Pg. 10, [0136]. Because the Rhodes '874 publication was able to record glucose values at oxygen concentrations as low as approximately 0.1 mg/L, the Rhodes '874 publication therefore shows a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.3 mg/L, as called for in claim 1.

There is no indication that the examiner applied any prior art references that taught a sensor system that measures glucose in a fluid with an oxygen concentration of less than about 0.3 mg/L, as called for in claims 1-9, 12, 15, and 29 of the Shults '352 patent. As outlined above, such limitation is taught by the Rhodes '874 publication. As such, the Rhodes '874 alone, or in combination with the Kerner publication, publication raises a substantial new question of patentability because a reasonable examiner would consider the teachings of the Rhodes '874 publication important in deciding whether claims 1-9, 12, 15, and 29 are patentable. See M.P.E.P. § 2242, Subtitle I, paragraph 3.

A detailed explanation of the pertinence and manner of applying the teachings of the Rhodes '874 publication to claim 1-9, 12, 15, and 29 is provided below in Section VI.

D. The Rhodes '874 publication raises an SNQ because the Rhodes '874 publication teaches a sensor system that is configured to have, in operation, a sensitivity of from about 5 pA/mg/dL to about 25 pA/mg/dL.

The Rhodes '874 publication was cited during prosecution of the Shults '352 patent, but the teachings of the Rhodes '874 publication were not applied against the claims of the Shults '352 patent. More specifically, the Rhodes '874 publication teaches a sensor system that is configured to have, in operation, a sensitivity of from about 5 pA/mg/dL to about 25 pA/mg/dL, as called for in claims 23, 24, 27, and 29-31 of the Shults '352 patent. There is no indication that the examiner found, considered, or applied any prior art reference that taught such limitation. In fact, the examiner explicitly stated that claim 23 (application claim 10) was allowable because the examiner did not identify art that includes a sensor system "configured to have, in operation, a sensitivity of from about 5 pA/mg/dL to about 25 pA/mg/dL." As such, a reasonable examiner would consider the teachings of the Rhodes '874 publication important in deciding whether claims 23, 24, 27, and 29-31 are patentable.

The Rhodes '874 publication is directed to the same problem as the Shults '352 patent. Namely, the Rhodes '874 publication is directed to the development of an implantable sensor system for subcutaneous glucose concentration measurements in low oxygen environments. See the Rhodes '874 publication, Abstract. More specifically, the Rhodes '874 publication discloses an implantable glucose sensor that showed no oxygen dependence to oxygen concentrations as low as 0.1 mg/L, and a sensitivity of at least 5.5 pA/mg/dL to increasing concentrations up to 400 mg/dL of glucose. See, for example, FIGs 3 and 9; pgs. 6-7, [0083]-[0085]; and pg. 11, [0131]-[0141]. As such, the disclosed sensor sensitivity of at least 5.5 pA/mg/dL in the Rhodes '874 publication falls within the claimed range of about 5 pA/mg/dL to about 25 pA/mg/dL in the Shults '352 patent.

There is no indication that the examiner applied any prior art references that taught a sensor system with a sensitivity falling within the claimed range of from about 5 pA/mg/dL to about 25 pA/mg/dL. As stated above, the Rhodes '874 publication teaches a sensor system with a sensitivity falling within the claimed range. As such, the Rhodes '874 publication alone, or in combination with the Kerner publication, raises a substantial new question of patentability

because a reasonable examiner would consider the teachings of the Rhodes '874 publication important in deciding whether claims 23, 24, 27, and 29-31 are patentable. See M.P.E.P. § 2242, Subtitle I, paragraph 3.

A detailed explanation of the pertinence and manner of applying the teachings of the Rhodes '874 publication to claims 23, 24, 27, and 29-31 is provided below in Section VI.

VI. DETAILED EXPLANATION OF MANNER AND PERTINENCE OF APPLYING THE CITED PRIOR ART TO EVERY CLAIM FOR WHICH REEXAMINATION IS REQUESTED (37 C.F.R. § 1.510(b)(2))

A. Claims 1, 3-6, 9, and 12 are anticipated under 35 U.S.C. § 102 by the Kusano publication.

Claims 1, 3-6, 9, and 12 are anticipated under 35 U.S.C. § 102(b) by the Kusano publication. Sections VI.A.1 – VI.A.7 detail how claims 1, 3-6, 9, and 12 are anticipated under 35 U.S.C. § 102(b) by the Kusano publication. For the examiner's convenience, the arguments presented below are summarized in the table provided in **Exhibit F**.

1. Independent Claim 1

Claim 1. A continuous glucose sensor system comprising:
Part of Claim 1

The Kusano publication teaches a continuous glucose sensor system. See, for example, the Kusano publication, Abstract, and Figures 3, 4, and 9. Figures 3, 4, and 9, for example, show continuous sensor readings over an extended period of time.

an implantable body comprising an electrode configured to measure a glucose level in a host;
Part of Claim 1

The Kusano publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Kusano publication pgs. 2-3, and Figure 2 (reproduced below).

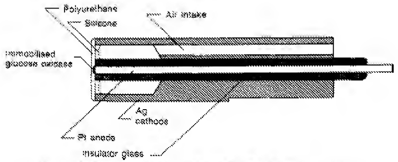


Figure 2. Schematic diagram of the experimental glucose electrode.

The Abstract of the Kusano publication, for example, states "[t]he electrode has been designed to be used with a percutaneous interface for future *in vivo* use."

> a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme configured to catalyze a reaction of glucose and oxygen; and
>
> *Part of Claim 1*

The Kusano publication teaches a polyurethane membrane disposed over the electrode. See, for example, Figure 2 (above). The membrane includes a resistance domain configured to limit transport of glucose to the electrode. See, for example, the Kusano publication, pgs. 1-3. Further, the sensor of the Kusano publication includes an enzyme configured to catalyze a reaction of glucose and oxygen. See *Id.*, and Figure 2.

> sensor electronics operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L.
>
> *Part of Claim 1*

The Kusano publication teaches sensor electronics operably connected to the electrode. The sensor electronics measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL, in a fluid with an oxygen concentration of less than about 0.3 mg/L. Specifically, the Kusano publication states, "The glucose electrode with percutaneous interface described in this paper differs from [previously described electrodes] using a novel approach to overcome the lack of oxygen in the interstitial fluid." *Id.* The Kusano publication further states:

> The electrode has a linear response to glucose concentration at an electrode output current ranging from 0 to 20nA ***even when the oxygen concentration of the glucose solution is zero***. The use of polyurethane as a diffusion barrier to glucose limits the electrode output current at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) to 20 nA. Therefore, the electrode can measure glucose concentrations up to 500 mg dl^{-1} (27.8 mmol l^{-1}) ***with no oxygen*** dissolved in the glucose solution.

The Kusano publication, Abstract (emphasis added).

Figure 8 of the Kusano publication (reproduced below) shows a linear current measurement up to 500 mg/dL, even at 0 kPa of Po_2.

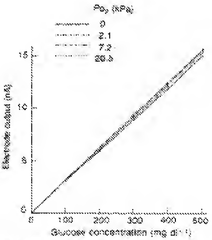


Figure 5. Electrode calibration curves under various Po_2.

The concluding remarks of the Kusano publication further state:

> Glucose concentrations of 0 to 500 mg dl^{-1} (27.8 mmol l^{-1}) could be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (21.7 kPa). Since the electrode is capable of operating where the oxygen concentration is low, it is thought to be suitable for implantation in subcutaneous tissue and may prove to be a key development in the realisation of a closed-loop artificial endocrine pancreas.

The Kusano publication, pg. 8.

The Kusano publication presents a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.3 mg/L, and thus falls within the scope of claim 1. Because the Kusano publication teaches each and every feature of claim 1, the Kusano publication anticipates claim 1 under 35 U.S.C. § 102(b).

2. Dependent Claim 3

In addition to showing each and every feature of claim 1, the Kusano publication discloses the features of claim 3, which depends from claim 1. Because the Kusano publication teaches each and every feature of claim 3, the Kusano publication anticipates claim 3 under 35 U.S.C. § 102(b).

Claim 3. The continuous glucose sensor system of claim 1, wherein the oxygen concentration is less than about 0.15 mg/L.

As discussed above, the Kusano publication teaches a sensor configured to measure glucose concentrations "even when the oxygen concentration of the glucose solution is zero."

The Kusano publication, Abstract. As such, the Kusano publication meets the claim limitation of the oxygen concentration being less than about 0.15 mg/L.

3. Dependent Claim 4

In addition to showing each and every feature of claim 1, the Kusano publication discloses the features of claim 4, which depends from claim 1. Because the Kusano publication teaches each and every feature of claim 4, the Kusano publication anticipates claim 4 under 35 U.S.C. § 102(b).

Claim 4. The continuous glucose sensor system of claim 1, wherein the oxygen concentration of is less than about 0.05 mg/L.

As discussed above, the Kusano publication teaches a sensor configured to measure glucose concentrations "even when the oxygen concentration of the glucose solution is zero." The Kusano publication, Abstract. As such, the Kusano publication meets the claim limitation of the oxygen concentration being less than about 0.05 mg/L.

4. Dependent Claim 5

In addition to showing each and every feature of claim 1, the Kusano publication discloses the features of claim 5, which depends from claim 1. Because the Kusano publication teaches each and every feature of claim 5, the Kusano publication anticipates claim 5 under 35 U.S.C. § 102(b).

Claim 5. The continuous glucose sensor system of claim 1, wherein the oxygen concentration of is less than about 0.02 mg/L.

As discussed above, the Kusano publication teaches a sensor configured to measure glucose concentrations "even when the oxygen concentration of the glucose solution is zero." The Kusano publication, Abstract. As such, the Kusano publication meets the claim limitation of the oxygen concentration being less than about 0.02 mg/L.

5. Dependent Claim 6

In addition to showing each and every feature of claim 1, the Kusano publication discloses the features of claim 6, which depends from claim 1. Because the Kusano publication teaches each and every feature of claim 6, the Kusano publication anticipates claim 6 under 35 U.S.C. § 102(b).

> Claim 6. The continuous glucose sensor system of claim 1, wherein the electrode comprises an exposed electroactive working electrode surface with a surface area of from about 0.00002 in^2 to about 0.0079 in^2.

The Kusano publication teaches an electroactive surface area that falls within the range of 0.00002 in^2 to about 0.0079 in^2. Specifically, the Kusano publication teaches a working electrode with "0.5 μg of albumin-linked glucose oxidase [] immobilised at the tip" of a "Pt wire 0.5 mm in diameter." See the Kusano publication, Abstract. The surface area of the electroactive surface is therefore the surface area of the tip of the Pt wire, which is equal to 0.000304 in^2 (Area = $\pi r^2 = (3.14)(0.25mm)^2 = 0.196\ mm^2 = 0.000304\ in^2$). A surface area of 0.000304 in^2 falls within the claimed range of about 0.00002 in^2 to about 0.0079 in^2.

6. Dependent Claim 9

In addition to showing each and every feature of claim 1, the Kusano publication discloses the features of claim 9, which depends from claim 1. Because the Kusano publication teaches each and every feature of claim 9, the Kusano publication anticipates claim 9 under 35 U.S.C. § 102(b).

> Claim 9. The continuous glucose sensor system of claim 1, wherein the sensor system is configured to have, in operation, a sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL.

The Kusano publication states, "In addition, the steady state current at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) should be less than the saturation current which results when the oxygen supplied from the air is limited, which is about 20 nA in this electrode." The Kusano publication, pg. 6. As such, the Kusano publication teaches a sensitivity of less than 40 pA/mg/dL (i.e., 20,000 pA divided by 500 mg dl^{-1}).

7. Dependent Claim 12

In addition to showing each and every feature of claim 1, the Kusano publication discloses the features of claim 12, which depends from claim 1. Because the Kusano publication teaches each and every feature of claim 12, the Kusano publication anticipates claim 12 under 35 U.S.C. § 102(b).

Claim 12. The continuous glucose sensor system of claim 1, wherein the resistance domain comprises a polyurethane.

The Kusano publication teaches the use of polyurethane to limit the penetration of glucose into the enzyme layer. See the Kusano publication, pg. 6.

B. Claims 2, 14-16, 18, and 21 are obvious under 35 U.S.C. § 103 in view of the Kusano publication and the Sternberg publication.

Claims 2, 14-16, 18, and 21 are unpatentable under 35 U.S.C. § 103(a) over the Kusano publication in view of the Sternberg publication. Sections VI.B.1 – VI.B.6 detail how claims 2, 14-16, 18, and 21 are rendered obvious by the teachings of the Kusano publication and the Sternberg publication. For the examiner's convenience, the arguments presented below are summarized in the table provided in **Exhibit G**.

1. Dependent Claim 2

As outlined above, the Kusano publication teaches each and every feature of claim 1. The combination of the Kusano publication and the Sternberg publication discloses the features of claim 2, which depends from claim 1. As such, claim 2 is unpatentable under 35 U.S.C. § 103(a)

Claim 2. The continuous glucose sensor system of claim 1, wherein the system is configured such that less than about 1μg of enzyme is consumed over 7 days of continuous operation.

The Sternberg publication describes three procedures for preparing electrodes with immobilized glucose oxidase (GOx). See, for example, the Sternberg publication, pgs. 2782-83, and Table I. Procedures "a," "b," and "c" contain 3.0 ± 1.2 μg, 6.4 ± 2.2 μg, and 10 ± 1.4 μg of GOx, respectively. *Id.* More specifically, procedure "a" provides 3.8 ± 1.5 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 3.0 ± 1.2 μg of enzyme; procedure "b" provides 8.0 ± 2.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 6.4 ± 2.2 μg of enzyme; and procedure "c" provides 13 ± 1.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 10 ± 1.4 μg of enzyme.

As discussed on page 2784 of the Sternberg publication, "Figure 5 compares the time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface."

The line noted with the "X" markers in Figure 5 (reproduced below) illustrates the consumption of GOx over about 15 days of continuous use.

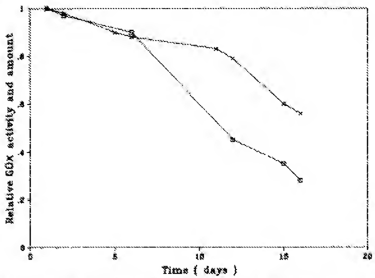


Figure 5. Relative evolution of surface GOx activity (O) and ^{125}I-GOx (X) in a CA-BSA-PBQ-GOx membrane not treated with lysine after coupling.

As shown in Figure 5, the relative consumption of GOx over the first seven days of use is between about 10% and about 15%. Enzyme prepared in accordance with procedure "a" would begin with 3.0 ± 1.2 μg, and result in a consumption of about 0.18-0.63 μg. Enzyme prepared in accordance with procedure "b" would begin with 6.4 ± 2.2 μg, and result in consumption of about 0.42-1.3 μg. Enzyme prepared in accordance with procedure "c" would begin with 10 ± 1.4 μg, and result in consumption of about 0.86-1.7 μg. As such, the Sternberg publication teaches how to configure the system to consume a range of enzyme mass from about 0.18-1.7 μg over 7 days of continuous operation.

One of skill in the art, in view of the teachings of the Sternberg publication, would thus appreciate how to configure the sensor "such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation." The sensor of claim 2 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 2 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kusano publication and the Sternberg publication. Claim 2 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

2. Independent Claim 14

> Claim 14. A continuous glucose sensor system comprising:
>
> *Part of Claim 14*

The Kusano publication teaches a continuous glucose sensor system. See, for example, the Kusano publication, Abstract, and Figures 3, 4, and 9. Figures 3, 4, and 9, for example, show continuous sensor readings over an extended period of time.

> an implantable body comprising an electrode configured to measure a glucose level in a host;
>
> *Part of Claim 14*

The Kusano publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Kusano publication pgs. 2-3, and Figure 2 (reproduced below).

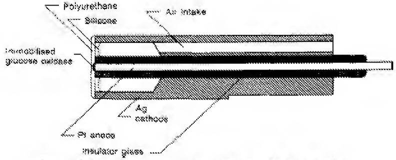


Figure 2. Schematic diagram of the experimental glucose electrode.

The Abstract of the Kusano publication, for example, states "[t]he electrode has been designed to be used with a percutaneous interface for future *in vivo* use."

> a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme configured to catalyze a reaction of glucose and oxygen; and
>
> *Part of Claim 14*

The Kusano publication teaches a polyurethane membrane disposed over the electrode. See, for example, Figure 2 (above). The membrane includes a resistance domain configured to limit transport of glucose to the electrode. See, for example, the Kusano publication, pgs. 1-3. Further, the sensor of the Kusano publication includes an enzyme configured to catalyze a reaction of glucose and oxygen. See *Id.*, and Figure 2.

> sensor electronics operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L,
>
> *Part of Claim 14*

The Kusano publication teaches sensor electronics operably connected to the electrode. The sensor electronics measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL, in a fluid with an oxygen concentration of less than about 0.6 mg/L. Specifically, the Kusano publication states, "The glucose electrode with percutaneous interface described in this paper differs from [previously described electrodes] using a novel approach to overcome the lack of oxygen in the interstitial fluid." *Id.* The Kusano publication further states:

> The electrode has a linear response to glucose concentration at an electrode output current ranging from 0 to 20nA ***even when the oxygen concentration of the glucose solution is zero***. The use of polyurethane as a diffusion barrier to glucose limits the electrode output current at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) to 20 nA. Therefore, the electrode can measure glucose concentrations up to 500 mg dl^{-1} (27.8 mmol l^{-1}) ***with no oxygen*** dissolved in the glucose solution.

The Kusano publication, Abstract (emphasis added).

Figure 8 of the Kusano publication (reproduced below) shows a linear current measurement up to 500 mg/dL, even at 0 kPa of Po_2.

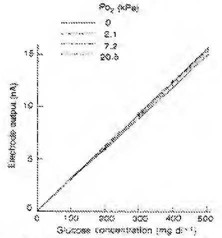


Figure 8. Electrode calibration curves under various Po_2

The concluding remarks of the Kusano publication further state:

> Glucose concentrations of 0 to 500 mg dl^{-1} (27.8 mmol l^{-1}) could be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (21.7 kPa). Since the electrode is capable of operating where the oxygen concentration is low, it is thought to be suitable for implantation in subcutaneous tissue and may prove to be a key development in the realisation of a closed-loop artificial endocrine pancreas.

The Kusano publication, pg. 8.

The Kusano publication presents a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.6 mg/L, and thus falls within the scope of claim 14.

> wherein the system is configured such that less than about 1μg of enzyme is consumed over 7 days of continuous operation.
>
> *Part of Claim 14*

The Sternberg publication describes three procedures for preparing electrodes with immobilized glucose oxidase (GOx). See, for example, the Sternberg publication, pgs. 2782-83, and Table I. Procedures "a," "b," and "c" contain 3.0 ± 1.2 μg, 6.4 ± 2.2 μg, and 10 ± 1.4 μg of GOx, respectively. *Id.* More specifically, procedure "a" provides 3.8 ± 1.5 $\mu g/cm^2$ on a membrane surface of 0.8 cm^2, which equates to 3.0 ± 1.2 μg of enzyme; procedure "b" provides 8.0 ± 2.8 $\mu g/cm^2$ on a membrane surface of 0.8 cm^2, which equates to 6.4 ± 2.2 μg of enzyme; and procedure "c" provides 13 ± 1.8 $\mu g/cm^2$ on a membrane surface of 0.8 cm^2, which equates to 10 ± 1.4 μg of enzyme.

As discussed on page 2784 of the Sternberg publication, "Figure 5 compares the time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface." The line noted with the "X" markers in Figure 5 (reproduced below) illustrates the consumption of GOx over about 15 days of continuous use.

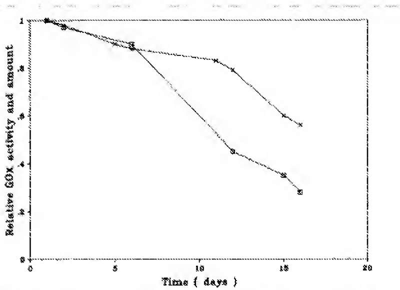


Figure 5. Relative evolution of surface GOx activity (O) and ^{125}I–GOx (X) in a CA–BSA–PBQ–GOx membrane not treated with lysine after coupling.

As shown in Figure 5, the relative consumption of GOx over the first seven days of use is between about 10% and about 15%. Enzyme prepared in accordance with procedure "a" would begin with 3.0 ± 1.2 μg, and result in a consumption of about 0.18-0.63 μg. Enzyme prepared in accordance with procedure "b" would begin with 6.4 ± 2.2 μg, and result in consumption of about 0.42-1.3 μg. Enzyme prepared in accordance with procedure "c" would begin with 10 ± 1.4 μg, and result in consumption of about 0.86-1.7 μg. As such, the Sternberg publication teaches how to configure the system to consume a range of enzyme mass from about 0.18-1.7 μg over 7 days of continuous operation.

One of skill in the art, in view of the teachings of the Sternberg publication, would thus appreciate how to configure the sensor "such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation." The sensor of claim 14 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 14 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kusano publication and the Sternberg publication. Claim 14 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

3. Dependent Claim 15

In addition to rendering claim 14 obvious, the combination of Kusano publication and the Sternberg publication discloses the features of claim 15, which depends from claim 14. As such, the Kusano publication and the Sternberg publication renders claim 15 obvious under 35 U.S.C. § 103(a).

Claim 15. The continuous glucose sensor system of claim 14, wherein the oxygen concentration is less than about 0.3 mg/L.

As discussed above, the Kusano publication teaches a sensor configured to measure glucose concentrations "even when the oxygen concentration of the glucose solution is zero." The Kusano publication, Abstract. As such, the Kusano publication meets the claim limitation of the oxygen concentration being less than about 0.3 mg/L.

4. Dependent Claim 16

In addition to rendering claim 14 obvious, the Kusano publication and the Sternberg publication discloses the features of claim 16, which depends from claim 14. As such, the Kusano publication and the Sternberg publication renders claim 16 obvious under 35 U.S.C. § 103(a).

Claim 16. The continuous glucose sensor system of claim 14, wherein the electrode comprises an exposed electroactive working electrode surface with a surface area of from about 0.00002 in^2 to about 0.0079 in^2.

The Kusano publication teaches an electroactive surface area that falls within the range of 0.00002 in^2 to about 0.0079 in^2. Specifically, the Kusano publication teaches a working electrode with "0.5 μg of albumin-linked glucose oxidase [] immobilised at the tip" of a "Pt wire 0.5 mm in diameter." See the Kusano publication, Abstract. The surface area of the electroactive surface is therefore the surface area of the tip of the Pt wire, which is equal to 0.000304 in^2 (Area = πr^2 = $(3.14)(0.25mm)^2$ = 0.196 mm^2 = 0.000304 in^2). A surface area of 0.000304 in^2 falls within the claimed range of about 0.00002 in^2 to about 0.0079 in^2.

5. Dependent Claim 18

In addition to rendering claim 14 obvious, the Kusano publication and the Sternberg publication discloses the features of claim 18, which depends from claim 14. As such, the

Kusano publication and the Sternberg publication renders claim 18 obvious under 35 U.S.C. § 103(a).

Claim 18. The continuous glucose sensor system of claim 14, wherein the sensor system is configured to have, in operation, a sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL.

The Kusano publication states, "In addition, the steady state current at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) should be less than the saturation current which results when the oxygen supplied from the air is limited, which is about 20 nA in this electrode." The Kusano publication, pg. 6. As such, the Kusano publication teaches a sensitivity of less than 40 pA/mg/dL (i.e., 20,000 pA divided by 500 mg dl^{-1}).

6. Dependent Claim 21

In addition to rendering claim 14 obvious, the Kusano publication and the Sternberg publication discloses the features of claim 21, which depends from claim 14. As such, the Kusano publication and the Sternberg publication renders claim 21 obvious under 35 U.S.C. § 103(a).

Claim 21. The continuous glucose sensor system of claim 14, wherein the resistance domain comprises a polyurethane.

The Kusano publication teaches the use of polyurethane to limit the penetration of glucose into the enzyme layer. See the Kusano publication, pg. 6.

C. Claims 7, 8, 17, 23, 27 and 29-31 are obvious under 35 U.S.C. § 103 in view of the Kusano publication and the Rhodes '874 publication.

Claims 7, 8, 17, 23, 27 and 29-31 are unpatentable under 35 U.S.C. § 103(a) over the Kusano publication in view of the Rhodes '874 publication. Sections VI.C.1 – VI.C.8 detail how claims 7, 8, 23, 27 and 29-31 are rendered obvious by the teachings of the Kusano publication and the Rhodes '874 publication. For the examiner's convenience, the arguments presented below are summarized in the table provided in **Exhibit H**.

1. Dependent Claim 7

As outlined above, the Kusano publication teaches each and every feature of claim 1. The combination of the Kusano publication and the Rhodes '874 publication discloses the features of claim 7, which depends from claim 1.

Claim 7. The continuous glucose sensor system of claim 1, wherein the resistance domain is configured to have a permeability ratio of at least about 50:1 of oxygen to glucose.

The Rhodes '874 publication teaches implantable glucose sensors employing multi-region membranes which have "enabled function of devices for over one year in vivo." The Rhodes '874 publication, pg. 5, [0061]. Specifically, the Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6-7, [0082]-[0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "a permeability ratio of at least about 50:1 of oxygen to glucose."

One of ordinary skill in the art would understand how to modify the resistance domain of the Kusano publication, in accordance with the teachings of the Rhodes '874 publication, to meet the claim limitation of "a permeability ratio of at least about 50:1 of oxygen to glucose." The sensor of claim 7 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 7 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kusano publication and the Rhodes '874 publication. Claim 7 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

2. Dependent Claim 8

As outlined above, the combination of the Kusano publication and the Rhodes '874 publication renders claim 7 obvious. The combination of the Kusano publication and the Rhodes '874 publication also teaches the features of claim 8, which depends from claim 7.

Claim 8. The continuous glucose sensor system of claim 7, wherein the resistance domain is configured to have a permeability ratio of at least about 200:1 of oxygen to glucose.

The Rhodes '874 publication teaches implantable glucose sensors employing multi-region membranes which have "enabled function of devices for over one year in vivo." The Rhodes '874 publication, pg. 5, [0061]. Specifically, the Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6-7, [0082]-[0084]. Specifically,

the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "a permeability ratio of at least about 200:1 of oxygen to glucose."

One of ordinary skill in the art would understand how to modify the resistance domain of the Kusano publication, in accordance with the teachings of the Rhodes '874 publication, to meet the claim limitation of "a permeability ratio of at least about 200:1 of oxygen to glucose." The sensor of claim 8 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 8 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kusano publication and the Rhodes '874 publication. Claim 8 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

3. Dependent Claim 17

As outlined above, the Kusano publication renders claim 14 obvious. The combination of the Kusano publication and the Rhodes '874 publication patent discloses the features of claim 17, which depends from claim 14.

> Claim 17. The continuous glucose sensor system of claim 14, wherein the resistance domain is configured to have a permeability ratio of at least about 50:1 of oxygen to glucose.

The Rhodes '874 publication teaches implantable glucose sensors employing multi-region membranes which have "enabled function of devices for over one year in vivo." The Rhodes '874 publication, pg. 5, [0061]. Specifically, the Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6-7, [0082]-[0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "a permeability ratio of at least about 50:1 of oxygen to glucose."

One of ordinary skill in the art would understand how to modify the resistance domain of the Kusano publication, in accordance with the teachings of the Rhodes '874 publication, to meet the claim limitation of "a permeability ratio of at least about 50:1 of oxygen to glucose." The sensor of claim 17 offers no more than the predictable use of prior art elements according to their

established functions. As such, claim 17 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kusano publication and the Rhodes '874 publication. Claim 17 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

4. Independent Claim 23

Claim 23. A continuous glucose sensor system comprising:
Part of Claim 23

The Kusano publication teaches a continuous glucose sensor system. See, for example, the Kusano publication, Abstract, and Figures 3, 4, and 9. Figures 3, 4, and 9, for example, show continuous sensor readings over an extended period of time.

an implantable body comprising an electrode configured to measure a glucose level in a host;
Part of Claim 23

The Kusano publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Kusano publication pgs. 2-3, and Figure 2 (reproduced below).

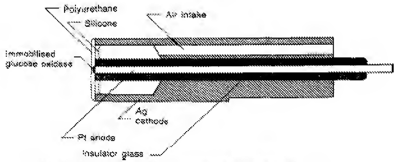


Figure 2. Schematic diagram of the experimental glucose electrode.

The Abstract of the Kusano publication, for example, states "[t]he electrode has been designed to be used with a percutaneous interface for future *in vivo* use."

> a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme configured to catalyze a reaction of glucose and oxygen; and
>
> *Part of Claim 23*

The Kusano publication teaches a polyurethane membrane disposed over the electrode. See, for example, Figure 2 (above). The membrane includes a resistance domain configured to limit transport of glucose to the electrode. See, for example, the Kusano publication, pgs. 1-3. Further, the sensor of the Kusano publication includes an enzyme configured to catalyze a reaction of glucose and oxygen. See *Id.*, and Figure 2.

> a sensor electronics unit operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L,
>
> *Part of Claim 23*

The Kusano publication teaches sensor electronics operably connected to the electrode. The sensor electronics measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL, in a fluid with an oxygen concentration of less than about 0.6 mg/L. Specifically, the Kusano publication states, "The glucose electrode with percutaneous interface described in this paper differs from [previously described electrodes] using a novel approach to overcome the lack of oxygen in the interstitial fluid." *Id.* The Kusano publication further states:

> The electrode has a linear response to glucose concentration at an electrode output current ranging from 0 to 20nA ***even when the oxygen concentration of the glucose solution is zero***. The use of polyurethane as a diffusion barrier to glucose limits the electrode output current at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) to 20 nA. Therefore, the electrode can measure glucose concentrations up to 500 mg dl^{-1} (27.8 mmol l^{-1}) ***with no oxygen*** dissolved in the glucose solution.

The Kusano publication, Abstract (emphasis added).

Figure 8 of the Kusano publication (reproduced below) shows a linear current measurement up to 500 mg/dL, even at 0 kPa of Po_2.

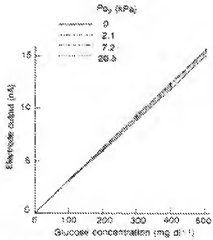


Figure 8. Electrode calibration curves under various P_{O_2}.

The concluding remarks of the Kusano publication further state:

> Glucose concentrations of 0 to 500 mg dl^{-1} (27.8 mmol l^{-1}) could be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (21.7 kPa). Since the electrode is capable of operating where the oxygen concentration is low, it is thought to be suitable for implantation in subcutaneous tissue and may prove to be a key development in the realisation of a closed-loop artificial endocrine pancreas.

The Kusano publication, pg. 8.

The Kusano publication presents a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.6 mg/L, and thus falls within the scope of claim 23.

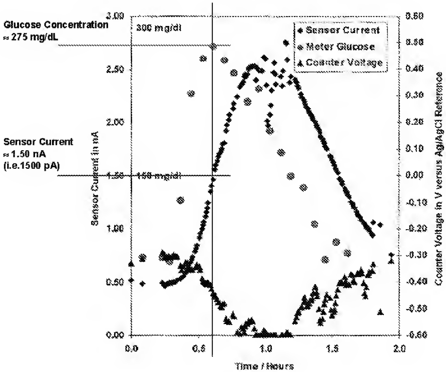
> wherein the sensor system is configured to have, in operation, a sensitivity of from about 5 pA/mg/dL to about 25 pA/mg/dL.
>
> *Part of Claim 23*

The Kusano publication states, "In addition, the steady state current at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) should be less than the saturation current which results when the oxygen supplied from the air is limited, which is about 20 nA in this electrode." The Kusano publication, pg. 6. As such, the Kusano publication teaches a sensitivity of less than 40 pA/mg/dL (i.e., 20,000 pA divided by 500 mg dl^{-1}).

The Rhodes '874 publication teaches a sensor system that is configured to have, in operation, a sensitivity of from about 5 pA/mg/dL to about 25 pA/mg/dL. More specifically, the

Rhodes '874 publication discloses an implantable glucose sensor that showed no oxygen dependence to oxygen concentrations as low as 0.1 mg/L, and a sensitivity of at least 5.5 pA/mg/dL to increasing concentrations up to 400 mg/dL) of glucose. See the Rhodes '874 publication, FIGs 3 and 9; and pg. 11, [0131]-[0141].

Figure 3 of the Rhodes '874 publication (reproduced below and annotated for clarity) shows a sensor system configured to have a sensor output of at least 5.5 pA/mg/dL between 0-300 mg/dL. For example, at a glucose concentration of 275 mg/dL, the glucose sensor system of the Rhodes '874 publication has a sensor current of 1.5 nA (i.e., 1500 pA). Therefore, the Rhodes '874 publication discloses a glucose sensor system that has a sensitivity of at least 5.5 pA/mg/dL. As such, the disclosed sensor sensitivity of at least 5.5 pA/mg/dL in the Rhodes '874 publication falls within the claimed range of about 5 pA/mg/dL to about 25 pA/mg/dL.



One of ordinary skill in the art would understand how to modify the sensitivity of the sensor system of the Kusano publication, in accordance with the teachings of the Rhodes '874 publication, to meet the claim limitation of "a sensitivity of from about 5 pA/mg/dL to about 25 pA/mg/dL." The sensor of claim 23 offers no more than the predictable use of prior art elements

according to their established functions. As such, claim 23 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kusano publication and the Rhodes '874 publication. Claim 23 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

5. Dependent Claim 27

In addition rendering claim 23 obvious, the combination of the Kusano publication and the Rhodes '874 publication discloses the features of claim 27, which depends from claim 23.

Claim 27. The continuous glucose sensor system of claim 23, wherein the resistance domain comprises a polyurethane.

The Kusano publication teaches the use of polyurethane to limit the penetration of glucose into the enzyme layer. See the Kusano publication, pg. 6.

6. Dependent Claim 29

In addition rendering claim 23 obvious, the combination of the Kusano publication and the Rhodes '874 publication discloses the features of claim 29, which depends from claim 23.

Claim 29. The continuous glucose sensor system of claim 23, wherein the oxygen concentration is less than about 0.3 mg/L.

As discussed above, the Kusano publication teaches a sensor configured to measure glucose concentrations "even when the oxygen concentration of the glucose solution is zero." The Kusano publication, Abstract. As such, the Kusano publication meets the claim limitation of the oxygen concentration being less than about 0.3 mg/L.

7. Dependent Claim 30

In addition rendering claim 23 obvious, the combination of the Kusano publication and the Rhodes '874 publication discloses the features of claim 30, which depends from claim 23.

Claim 30. The continuous glucose sensor system of claim 23, wherein the electrode comprises an exposed electroactive working electrode surface with a surface area of from about 0.00002 in^2 to about 0.0079 in^2.

The Kusano publication teaches an electroactive surface area that falls within the range of 0.00002 in^2 to about 0.0079 in^2. Specifically, the Kusano publication teaches a working electrode with "0.5 μg of albumin-linked glucose oxidase [] immobilised at the tip" of a "Pt wire

0.5 mm in diameter." See the Kusano publication, Abstract. The surface area of the electroactive surface is therefore the surface area of the tip of the Pt wire, which is equal to 0.000304 in^2 (Area = πr^2 = (3.14)(0.25mm)^2 = 0.196 mm^2 = 0.000304 in^2). A surface area of 0.000304 in^2 falls within the claimed range of about 0.00002 in^2 to about 0.0079 in^2.

8. Dependent Claim 31

In addition rendering claim 23 obvious, the combination of the Kusano publication and the Rhodes '874 publication discloses the features of claim 31, which depends from claim 23.

> Claim 31. The continuous glucose sensor system of claim 23, wherein the resistance domain is configured to have a permeability ratio of at least about 50:1 of oxygen to glucose.

The Rhodes '874 publication teaches implantable glucose sensors employing multi-region membranes which have "enabled function of devices for over one year in vivo." The Rhodes '874 publication, pg. 5, [0061]. Specifically, the Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6-7, [0082]-[0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "a permeability ratio of at least about 50:1 of oxygen to glucose."

One of ordinary skill in the art would understand how to modify the resistance domain of the Kusano publication, in accordance with the teachings of the Rhodes '874 publication, to meet the claim limitation of "a permeability ratio of at least about 50:1 of oxygen to glucose." The sensor of claim 31 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 31 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kusano publication and the Rhodes '874 publication. Claim 31 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

D. Claim 24 is obvious under 35 U.S.C. § 103 in view of the Kusano publication, the Rhodes '874 publication, and the Sternberg publication.

As discussed above, claim 23 is rendered obvious by the teachings of the Kusano publication and the Rhodes '874 publication. As outlined below, the combination of the Kusano

publication, the Rhodes '874 publication, and the Sternberg publication renders claim 24, which depends from claim 23, obvious. For the examiner's convenience, the arguments presented below are summarized in the table provided in **Exhibit I**.

Claim 24. The continuous glucose sensor system of claim 23, wherein the system is configured such that less than about 1μg of enzyme is consumed over 10 days of continuous operation.

The Sternberg publication describes three procedures for preparing electrodes with immobilized glucose oxidase (GOx). See, for example, the Sternberg publication, pgs. 2782-83, and Table I. Procedures "a," "b," and "c" contain 3.0 ± 1.2 μg, 6.4 ± 2.2 μg, and 10 ± 1.4 μg of GOx, respectively. *Id.* More specifically, procedure "a" provides 3.8 ± 1.5 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 3.0 ± 1.2 μg of enzyme; procedure "b" provides 8.0 ± 2.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 6.4 ± 2.2 μg of enzyme; and procedure "c" provides 13 ± 1.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 10 ± 1.4 μg of enzyme.

As discussed on page 2784 of the Sternberg publication, "Figure 5 compares the time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface." The line noted with the "X" markers in Figure 5 (reproduced below) illustrates the consumption of GOx over about 15 days of continuous use.

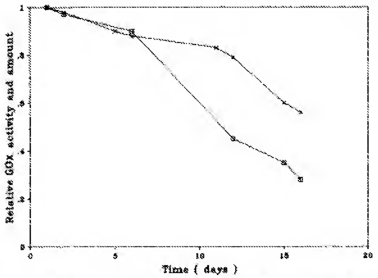


Figure 5. Relative evolution of surface GOx activity (O) and ^{125}I–GOx (X) in a CA–BSA–PBQ–GOx membrane not treated with lysine after coupling.

As shown in Figure 5, the relative consumption of GOx over the first ten days of use is between about 15% and about 20%. Enzyme prepared in accordance with procedure "a" would begin with 3.0 ± 1.2 μg, and result in a consumption of about 0.27-0.84 μg. Enzyme prepared in accordance with procedure "b" would begin with 6.4 ± 2.2 μg, and result in consumption of about 0.63-1.7 μg. Enzyme prepared in accordance with procedure "c" would begin with 10 ± 1.4 μg, and result in consumption of about 1.3-2.3 μg. As such, the Sternberg publication teaches how to configure the system to consume a range of enzyme mass from about 0.27-2.3 μg over 10 days of continuous operation.

One of skill in the art, in view of the teachings of the Sternberg publication, would thus appreciate how to configure the sensor "such that less than about 1 μg of enzyme is consumed over 10 days of continuous operation." The sensor of claim 24 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 24 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kusano publication, the Rhodes '874 publication, and the Sternberg publication. Claim 24 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

E. Claims 1, 3-6, 9, and 12, are obvious under 35 U.S.C. § 103 in view of the Kerner publication and the Kusano publication.

Claims 1, 3-6, 9, and 12 are unpatentable under 35 U.S.C. § 103(a) over the Kerner publication in view of the Kusano publication. Sections VI.E.1 – VI.E.7 detail how claims 1, 3-6, 9, and 12 are rendered obvious by the combination of the Kerner publication and the Kusano publication. For the examiner's convenience, the arguments presented below are summarized in the table provided in **Exhibit J**.

1. Independent Claim 1

Claim 1.	A continuous glucose sensor system comprising:
	Part of Claim 1

The Kerner publication teaches a continuous glucose sensor system. See, for example, the Kerner publication, Summary, pg. 9, and FIG. 1.

The Kusano publication teaches a continuous glucose sensor system. See the Kusano publication, Abstract, and Figures 3, 4, and 9. Figures 3, 4, and 9, for example, show continuous sensor readings over an extended period of time.

> an implantable body comprising an electrode configured to measure a glucose level in a host;
>
> *Part of Claim 1*

The Kerner publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See the Kerner publication, Summary, pg. 9, and FIG. 1.

The Kusano publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Kusano publication pgs. 2-3, and Figure 2 (reproduced below).

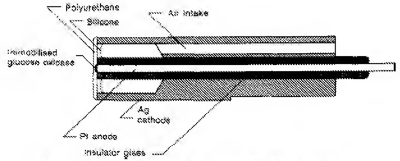


Figure 2. Schematic diagram of the experimental glucose electrode

The Abstract of the Kusano publication, for example, states "[t]he electrode has been designed to be used with a percutaneous interface for future *in vivo* use."

> a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme configured to catalyze a reaction of glucose and oxygen; and
>
> *Part of Claim 1*

The Kerner publication teaches a membrane disposed over the electrode, wherein the membrane includes a resistance domain configured to limit transport of glucose to the electrode and an enzyme to catalyze a reaction of glucose and oxygen. See the Kerner publication, Summary, pg. 9, and FIG. 1.

The Kusano publication teaches a polyurethane membrane disposed over the electrode. See, for example, Figure 2 (above). The membrane includes a resistance domain configured to

limit transport of glucose to the electrode. See, for example, the Kusano publication, pgs. 1-3. Further, the sensor of the Kusano publication includes an enzyme configured to catalyze a reaction of glucose and oxygen. See *Id.*, and Figure 2.

> sensor electronics operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L.
>
> *Part of Claim 1*

The Kerner publication teaches sensor electronics operably connected to the electrode. The electronics unit is configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of above 0.5 mg/L. See the Kerner publication, Summary, FIGs. 4 and 5, and pg. 11.

The Kusano publication teaches sensor electronics operably connected to the electrode. The sensor electronics measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL, in a fluid with an oxygen concentration of less than about 0.3 mg/L. Specifically, the Kusano publication states, "The glucose electrode with percutaneous interface described in this paper differs from [previously described electrodes] using a novel approach to overcome the lack of oxygen in the interstitial fluid." *Id.* The Kusano publication further states:

> The electrode has a linear response to glucose concentration at an electrode output current ranging from 0 to 20nA ***even when the oxygen concentration of the glucose solution is zero***. The use of polyurethane as a diffusion barrier to glucose limits the electrode output current at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) to 20 nA. Therefore, the electrode can measure glucose concentrations up to 500 mg dl^{-1} (27.8 mmol l^{-1}) ***with no oxygen*** dissolved in the glucose solution.

The Kusano publication, Abstract (emphasis added).

Figure 8 of the Kusano publication (reproduced below) shows a linear current measurement up to 500 mg/dL, even at 0 kPa of Po_2.

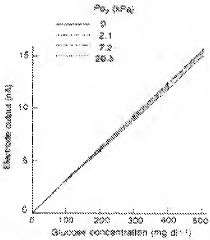


Figure 8. Electrode calibration curves under various Po_2.

The concluding remarks of the Kusano publication further state:

> Glucose concentrations of 0 to 500 mg dl^{-1} (27.8 mmol l^{-1}) could be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (21.7 kPa). Since the electrode is capable of operating where the oxygen concentration is low, it is thought to be suitable for implantation in subcutaneous tissue and may prove to be a key development in the realisation of a closed-loop artificial endocrine pancreas.

The Kusano publication, pg. 8.

The Kusano publication presents a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.3 mg/L, and thus falls within the scope of claim 1.

One of ordinary skill in the art would understand how to modify the sensor of the Kerner publication, in accordance with the teachings of the Kusano publication to meet the claim limitation of "sensor electronics … configured to measure a current produced by the electrode … in a fluid with an oxygen concentration of less than about 0.3 mg/L." The sensor of claim 1 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 1 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication and the Kusano publication. Claim 1 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

2. Dependent Claim 3

In addition to rendering claim 1 obvious, the combination of the Kerner publication and the Kusano publication discloses the features of claim 3, which depends from claim 1.

Claim 3. The continuous glucose sensor system of claim 1, wherein the oxygen concentration is less than about 0.15 mg/L.

As discussed above, the Kusano publication teaches a sensor configured to measure glucose concentrations "even when the oxygen concentration of the glucose solution is zero." The Kusano publication, Abstract. As such, the Kusano publication meets the claim limitation of the oxygen concentration being less than about 0.15 mg/L.

The sensor of claim 3 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 3 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication and the Kusano publication. Claim 3 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

3. Dependent Claim 4

In addition to rendering claim 1 obvious, the combination of the Kerner publication and the Kusano publication discloses the features of claim 4, which depends from claim 1.

Claim 4. The continuous glucose sensor system of claim 1, wherein the oxygen concentration of is less than about 0.05 mg/L.

As discussed above, the Kusano publication teaches a sensor configured to measure glucose concentrations "even when the oxygen concentration of the glucose solution is zero." The Kusano publication, Abstract. As such, the Kusano publication meets the claim limitation of the oxygen concentration being less than about 0.05 mg/L.

The sensor of claim 4 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 4 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication and the Kusano publication. Claim 4 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

4. Dependent Claim 5

In addition to rendering claim 1 obvious, the combination of the Kerner publication and the Kusano publication discloses the features of claim 5, which depends from claim 1.

Claim 5. The continuous glucose sensor system of claim 1, wherein the oxygen concentration of is less than about 0.02 mg/L.

As discussed above, the Kusano publication teaches a sensor configured to measure glucose concentrations "even when the oxygen concentration of the glucose solution is zero." The Kusano publication, Abstract. As such, the Kusano publication meets the claim limitation of the oxygen concentration being less than about 0.02 mg/L.

The sensor of claim 5 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 5 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication and the Kusano publication. Claim 5 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

5. Dependent Claim 6

In addition to rendering claim 1 obvious, the combination of the Kerner publication and the Kusano publication discloses the features of claim 6, which depends from claim 1.

Claim 6. The continuous glucose sensor system of claim 1, wherein the electrode comprises an exposed electroactive working electrode surface with a surface area of from about 0.00002 in^2 to about 0.0079 in^2.

The Kerner publication teaches the electrode includes an exposed electroactive working electrode surface with a surface area between about 0.00002 in^2 and about 0.0079 in^2. See the Kerner publication, pg. 9. The diameter of the working electrode is 0.5 mm (0.0197 in; surface area of about 0.000304 in^2). *Id.*

The Kusano publication teaches an electroactive surface area that falls within the range of 0.00002 in^2 to about 0.0079 in^2. Specifically, the Kusano publication teaches a working electrode with "0.5 μg of albumin-linked glucose oxidase [] immobilised at the tip" of a "Pt wire 0.5 mm in diameter." See the Kusano publication, Abstract. The surface area of the electroactive surface is therefore the surface area of the tip of the Pt wire, which is equal to

0.000304 in^2 (Area = $\pi r^2 = (3.14)(0.25mm)^2 = 0.196\ mm^2 = 0.000304\ in^2$). A surface area of 0.000304 in^2 falls within the claimed range of about 0.00002 in^2 to about 0.0079 in^2.

The sensor of claim 6 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 6 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication and the Kusano publication. Claim 6 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

6. Dependent Claim 9

In addition to rendering claim 1 obvious, the combination of the Kerner publication and the Kusano publication discloses the features of claim 9, which depends from claim 1.

Claim 9. The continuous glucose sensor system of claim 1, wherein the sensor system is configured to have, in operation, a sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL.

The Kerner publication teaches the sensor system is configured to have, in operation, a sensitivity of from about 4.1 to 4.9 nA at 100 mg/dL (i.e., 41 to 49 pA/mg/dL), which falls within the claimed range of 1 pA/mg/dL to about 100 pA/mg/dL. See the Kerner publication, FIG. 4, and pg. 11.

The Kusano publication states, "In addition, the steady state current at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) should be less than the saturation current which results when the oxygen supplied from the air is limited, which is about 20 nA in this electrode." The Kusano publication, pg. 6. As such, the Kusano publication teaches a sensitivity of less than 40 pA/mg/dL (i.e., 20,000 pA divided by 500 mg dl^{-1}), which falls within the claimed sensitivity range.

The sensor of claim 9 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 9 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication and the Kusano publication. Claim 9 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

7. Dependent Claim 12

In addition to rendering claim 1 obvious, the combination of the Kerner publication and the Kusano publication discloses the features of claim 12, which depends from claim 1.

Claim 12. The continuous glucose sensor system of claim 1, wherein the resistance domain comprises a polyurethane.

The Kusano publication teaches the use of polyurethane to limit the penetration of glucose into the enzyme layer. See the Kusano publication, pg. 6.

The sensor of claim 12 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 12 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication and the Kusano publication. Claim 12 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

F. Claims 2, 14-16, 18, and 21 are obvious under 35 U.S.C. § 103 in view of the Kerner publication, the Kusano publication, and the Sternberg publication.

Claims 2, 14-16, 18, and 21 are unpatentable under 35 U.S.C. § 103(a) over the Kerner publication, the Kusano publication, and the Sternberg publication. Sections VI.F.1 – VI.F.6 detail how claims 2, 14-16, 18, and 21 are rendered obvious by the combination of the Kerner publication, the Kusano publication, and the Sternberg publication. For the examiner's convenience, the arguments presented below are summarized in the table provided in **Exhibit K**.

1. Dependent Claim 2

As outlined above, claim 1 is rendered obvious by the combination of the Kerner publication and the Kusano publication. Claim 2, which depends from claim 1, is rendered obvious to one of skill in the art by the combination of the Kerner publication, the Kusano publication, and the Sternberg publication. As such, claim 2 is unpatentable under 35 U.S.C. § 103(a)

Claim 2. The continuous glucose sensor system of claim 1, wherein the system is configured such that less than about 1μg of enzyme is consumed over 7 days of continuous operation.

The Sternberg publication describes three procedures for preparing electrodes with immobilized glucose oxidase (GOx). See, for example, the Sternberg publication, pgs. 2782-83, and Table I. Procedures "a," "b," and "c" contain 3.0 ± 1.2 μg, 6.4 ± 2.2 μg, and 10 ± 1.4 μg of GOx, respectively. *Id.* More specifically, procedure "a" provides 3.8 ± 1.5 $\mu g/cm^2$ on a membrane surface of 0.8 cm^2, which equates to 3.0 ± 1.2 μg of enzyme; procedure "b" provides 8.0 ± 2.8 $\mu g/cm^2$ on a membrane surface of 0.8 cm^2, which equates to 6.4 ± 2.2 μg of enzyme; and procedure "c" provides 13 ± 1.8 $\mu g/cm^2$ on a membrane surface of 0.8 cm^2, which equates to 10 ± 1.4 μg of enzyme.

As discussed on page 2784 of the Sternberg publication, "Figure 5 compares the time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface." The line noted with the "X" markers in Figure 5 (reproduced below) illustrates the consumption of GOx over about 15 days of continuous use.

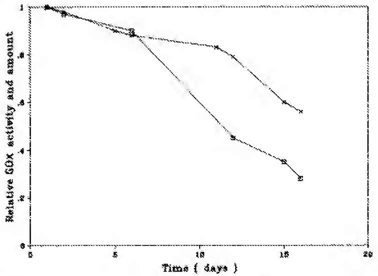


Figure 5. Relative evolution of surface GOx activity (O) and ^{125}I-GOx (X) in a CA-BSA-PBQ-GOx membrane not treated with lysine after coupling.

As shown in Figure 5, the relative consumption of GOx over the first seven days of use is between about 10% and about 15%. Enzyme prepared in accordance with procedure "a" would begin with 3.0 ± 1.2 μg, and result in a consumption of about 0.18-0.63 μg. Enzyme prepared in

accordance with procedure "b" would begin with 6.4 ± 2.2 μg, and result in consumption of about 0.42-1.3 μg. Enzyme prepared in accordance with procedure "c" would begin with 10 ± 1.4 μg, and result in consumption of about 0.86-1.7 μg. As such, the Sternberg publication teaches how to configure the system to consume a range of enzyme mass from about 0.18-1.7 μg over 7 days of continuous operation.

One of skill in the art, in view of the teachings of the Sternberg publication, would thus appreciate how to configure the sensor "such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation." The sensor of claim 2 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 2 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication, the Kusano publication, and the Sternberg publication. Claim 2 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

2. Independent Claim 14

Claim 14. A continuous glucose sensor system comprising: *Part of Claim 14*

The Kerner publication teaches a continuous glucose sensor system. See, for example, the Kerner publication, Summary, pg. 9, and FIG. 1.

The Kusano publication teaches a continuous glucose sensor system. See the Kusano publication, Abstract, and Figures 3, 4, and 9. Figures 3, 4, and 9, for example, show continuous sensor readings over an extended period of time.

an implantable body comprising an electrode configured to measure a glucose level in a host; *Part of Claim 14*

The Kerner publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See the Kerner publication, Summary, pg. 9, and FIG. 1.

The Kusano publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Kusano publication pgs. 2-3, and Figure 2 (reproduced below).

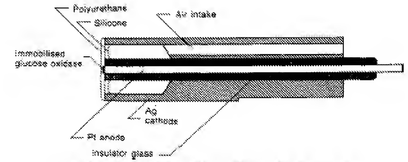


Figure 2. Schematic diagram of the experimental glucose electrode.

The Abstract of the Kusano publication, for example, states "[t]he electrode has been designed to be used with a percutaneous interface for future *in vivo* use."

> a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme configured to catalyze a reaction of glucose and oxygen; and
>
> *Part of Claim 14*

The Kerner publication teaches a membrane disposed over the electrode, wherein the membrane includes a resistance domain configured to limit transport of glucose to the electrode and an enzyme to catalyze a reaction of glucose and oxygen. See the Kerner publication, Summary, pg. 9, and FIG. 1.

The Kusano publication teaches a polyurethane membrane disposed over the electrode. See, for example, Figure 2 (above). The membrane includes a resistance domain configured to limit transport of glucose to the electrode. See, for example, the Kusano publication, pgs. 1-3. Further, the sensor of the Kusano publication includes an enzyme configured to catalyze a reaction of glucose and oxygen. See *Id.*, and Figure 2.

> sensor electronics operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L,
>
> *Part of Claim 14*

The Kerner publication teaches sensor electronics operably connected to the electrode. The electronics unit is configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L. See the Kerner publication, Summary, FIGs. 4 and 5,

and pg. 11. Specifically, the Kerner publication teaches and oxygen concentrations above 0.5 mg/L, which includes concentrations of less than about 0.6 mg/L. *Id.*

The Kusano publication teaches sensor electronics operably connected to the electrode. The sensor electronics measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL, in a fluid with an oxygen concentration of less than about 0.6 mg/L. Specifically, the Kusano publication states, "The glucose electrode with percutaneous interface described in this paper differs from [previously described electrodes] using a novel approach to overcome the lack of oxygen in the interstitial fluid." *Id.* The Kusano publication further states:

> The electrode has a linear response to glucose concentration at an electrode output current ranging from 0 to 20nA ***even when the oxygen concentration of the glucose solution is zero***. The use of polyurethane as a diffusion barrier to glucose limits the electrode output current at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) to 20 nA. Therefore, the electrode can measure glucose concentrations up to 500 mg dl^{-1} (27.8 mmol l^{-1}) ***with no oxygen*** dissolved in the glucose solution.

The Kusano publication, Abstract (emphasis added).

Figure 8 of the Kusano publication (reproduced below) shows a linear current measurement up to 500 mg/dL, even at 0 kPa of Po_2.

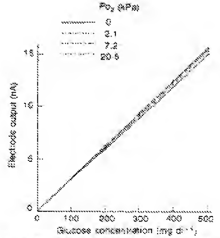


Figure 8. Electrode calibration curves under various Po_2

The concluding remarks of the Kusano publication further state:

> Glucose concentrations of 0 to 500 mg dl^{-1} (27.8 mmol l^{-1}) could be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (21.7 kPa). Since the electrode is capable of operating where the oxygen concentration is low, it is thought to be suitable for implantation in subcutaneous tissue and may prove to be a key development in the realisation of a closed-loop artificial endocrine pancreas.

The Kusano publication, pg. 8.

> wherein the system is configured such that less than about 1μg of enzyme is consumed over 7 days of continuous operation.
>
> *Part of Claim 14*

The Sternberg publication describes three procedures for preparing electrodes with immobilized glucose oxidase (GOx). See, for example, the Sternberg publication, pgs. 2782-83, and Table I. Procedures "a," "b," and "c" contain 3.0 ± 1.2 μg, 6.4 ± 2.2 μg, and 10 ± 1.4 μg of GOx, respectively. *Id.* More specifically, procedure "a" provides 3.8 ± 1.5 $\mu g/cm^2$ on a membrane surface of 0.8 cm^2, which equates to 3.0 ± 1.2 μg of enzyme; procedure "b" provides 8.0 ± 2.8 $\mu g/cm^2$ on a membrane surface of 0.8 cm^2, which equates to 6.4 ± 2.2 μg of enzyme; and procedure "c" provides 13 ± 1.8 $\mu g/cm^2$ on a membrane surface of 0.8 cm^2, which equates to 10 ± 1.4 μg of enzyme.

As discussed on page 2784 of the Sternberg publication, "Figure 5 compares the time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface." The line noted with the "X" markers in Figure 5 (reproduced below) illustrates the consumption of GOx over about 15 days of continuous use.

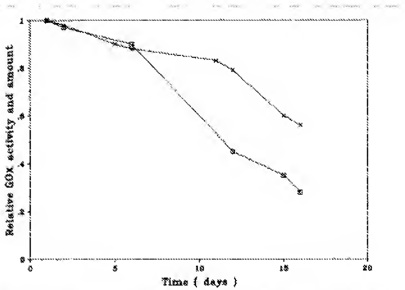


Figure 5. Relative evolution of surface GOx activity (O) and ^{125}I-GOx (X) in a CA-BSA-PBQ-GOx membrane not treated with lysine after coupling.

As shown in Figure 5, the relative consumption of GOx over the first seven days of use is between about 10% and about 15%. Enzyme prepared in accordance with procedure "a" would begin with 3.0 ± 1.2 μg, and result in a consumption of about 0.18-0.63 μg. Enzyme prepared in accordance with procedure "b" would begin with 6.4 ± 2.2 μg, and result in consumption of about 0.42-1.3 μg. Enzyme prepared in accordance with procedure "c" would begin with 10 ± 1.4 μg, and result in consumption of about 0.86-1.7 μg. As such, the Sternberg publication teaches how to configure the system to consume a range of enzyme mass from about 0.18-1.7 μg over 7 days of continuous operation.

One of skill in the art, in view of the teachings of the Sternberg publication, would thus appreciate how to configure the sensor "such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation." The sensor of claim 14 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 14 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication, the Kusano publication, and the Sternberg publication. Claim 14 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

3. Dependent Claim 15

In addition to rendering claim 14 obvious, the combination of the Kerner publication, the Kusano publication, and the Sternberg publication discloses the features of claim 15, which depends from claim 14.

Claim 15. The continuous glucose sensor system of claim 14, wherein the oxygen concentration is less than about 0.3 mg/L.

The Kerner publication teaches sensor electronics operably connected to the electrode. The electronics unit is configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of above 0.5 mg/L. See the Kerner publication, Summary, FIGs. 4 and 5, and pg. 11.

The Kusano publication teaches a sensor configured to measure glucose concentrations "even when the oxygen concentration of the glucose solution is zero." The Kusano publication, Abstract. As such, the Kusano publication meets the claim limitation of the oxygen concentration being less than about 0.3 mg/L. The Kusano publication presents a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.3 mg/L, and thus falls within the scope of claim 15.

One of ordinary skill in the art would understand how to modify the sensor of the Kerner publication, in accordance with the teachings of the Kusano publication to meet the claim limitation of "sensor electronics … configured to measure a current produced by the electrode … in a fluid with an oxygen concentration of less than about 0.3 mg/L." The sensor of claim 15 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 15 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication, the Kusano publication, and the Sternberg publication. Claim 15 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

4. Dependent Claim 16

In addition to rendering claim 14 obvious, the combination of the Kerner publication, the Kusano publication, and the Sternberg publication discloses the features of claim 16, which depends from claim 14.

Claim 16. The continuous glucose sensor system of claim 14, wherein the electrode comprises an exposed electroactive working electrode surface with a surface area of from about 0.00002 in^2 to about 0.0079 in^2.

The Kerner publication teaches the electrode includes an exposed electroactive working electrode surface with a surface area between about 0.00002 in^2 and about 0.0079 in^2. See the Kerner publication, pg. 9. The diameter of the working electrode is 0.5 mm (0.0197 in; surface area of about 0.000304 in^2). *Id.*

The Kusano publication teaches an electroactive surface area that falls within the range of 0.00002 in^2 to about 0.0079 in^2. Specifically, the Kusano publication teaches a working electrode with "0.5 μg of albumin-linked glucose oxidase [] immobilised at the tip" of a "Pt wire 0.5 mm in diameter." See the Kusano publication, Abstract. The surface area of the electroactive surface is therefore the surface area of the tip of the Pt wire, which is equal to 0.000304 in^2 (Area = $\pi r^2 = (3.14)(0.25mm)^2 = 0.196\ mm^2 = 0.000304\ in^2$). A surface area of 0.000304 in^2 falls within the claimed range of about 0.00002 in^2 to about 0.0079 in^2.

The sensor of claim 16 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 16 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication, the Kusano publication, and the Sternberg publication. Claim 16 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

5. Dependent Claim 18

In addition to rendering claim 14 obvious, the combination of the Kerner publication, the Kusano publication, and the Sternberg publication discloses the features of claim 18, which depends from claim 14.

Claim 18. The continuous glucose sensor system of claim 14, wherein the sensor system is configured to have, in operation, a sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL.

The Kerner publication teaches the sensor system is configured to have, in operation, a sensitivity of from about 4.1 to 4.9 nA at 100 mg/dL (i.e., 41 to 49 pA/mg/dL), which falls within the claimed range of 1 pA/mg/dL to about 100 pA/mg/dL. See the Kerner publication, FIG. 4, and pg. 11.

The Kusano publication states, "In addition, the steady state current at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) should be less than the saturation current which results when the oxygen supplied from the air is limited, which is about 20 nA in this electrode." The Kusano publication, pg. 6. As such, the Kusano publication teaches a sensitivity of less than 40 pA/mg/dL (i.e., 20,000 pA divided by 500 mg dl^{-1}), which falls within the claimed sensitivity range of claim 18.

The sensor of claim 18 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 18 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication, the Kusano publication, and the Sternberg publication. Claim 18 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

6. Dependent Claim 21

In addition to rendering claim 14 obvious, the combination of the Kerner publication, the Kusano publication, and the Sternberg publication discloses the features of claim 21, which depends from claim 14. As such, the combination renders claim 21 obvious under 35 U.S.C. § 103(a).

Claim 21. The continuous glucose sensor system of claim 14, wherein the resistance domain comprises a polyurethane.

The Kusano publication teaches the use of polyurethane to limit the penetration of glucose into the enzyme layer. See the Kusano publication, pg. 6.

The sensor of claim 21 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 21 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication, the Kusano publication, and the Sternberg publication. Claim 21 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

G. Claims 7, 8, 17, 23, 27 and 29-31 are obvious under 35 U.S.C. § 103 in view of the Kerner publication, the Kusano publication, and the Rhodes '874 publication.

Claims 7, 8, 17, 23, 27 and 29-31 are unpatentable under 35 U.S.C. § 103(a) over the Kerner publication in view of the Kusano publication, and further in view of the Rhodes '874 publication. Sections VI.G.1 – VI.G.8 detail how claims 7, 8, 17, 23, 27 and 29-31 are rendered

obvious by the teachings of the Kerner publication, the Kusano publication, and the Rhodes '874 publication. For the examiner's convenience, the arguments presented below are summarized in the table provided in **Exhibit L**.

1. Dependent Claim 7

As outlined above, the combination of the Kerner publication and the Kusano publication renders claim 1 obvious. The Rhodes '874 publication discloses the features of claim 7, which depends from claim 1.

Claim 7. The continuous glucose sensor system of claim 1, wherein the resistance domain is configured to have a permeability ratio of at least about 50:1 of oxygen to glucose.

The Rhodes '874 publication teaches implantable glucose sensors employing multi-region membranes which have "enabled function of devices for over one year in vivo." The Rhodes '874 publication, pg. 5, [0061]. Specifically, the Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having the desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6-7, [0082]-[0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "a permeability ratio of at least about 50:1 of oxygen to glucose."

One of ordinary skill in the art would understand how to modify the resistance domain of the Kerner publication and the Kusano publication, in accordance with the teachings of the Rhodes '874 publication, to meet the claim limitation of "a permeability ratio of at least about 50:1 of oxygen to glucose." The sensor of claim 7 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 7 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication, the Kusano publication, and the Rhodes '874 publication. Claim 7 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

2. Dependent Claim 8

As outlined above, the combination of the Kerner publication, the Kusano publication, and the Rhodes '874 publication renders claim 7 obvious. The combination also teaches the features of claim 8, which depends from claim 7.

> Claim 8. The continuous glucose sensor system of claim 7, wherein the resistance domain is configured to have a permeability ratio of at least about 200:1 of oxygen to glucose.

The Rhodes '874 publication teaches implantable glucose sensors employing multi-region membranes which have "enabled function of devices for over one year in vivo." The Rhodes '874 publication, pg. 5, [0061]. Specifically, the Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having the desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6-7, [0082]-[0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "a permeability ratio of at least about 200:1 of oxygen to glucose."

One of ordinary skill in the art would understand how to modify the resistance domain of the Kerner publication and the Kusano publication, in accordance with the teachings of the Rhodes '874 publication, to meet the claim limitation of "a permeability ratio of at least about 200:1 of oxygen to glucose." The sensor of claim 8 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 8 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication, the Kusano publication, and the Rhodes '874 publication. Claim 8 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

3. Dependent Claim 17

As outlined above, the combination of the Kerner publication and the Kusano publication renders claim 14 obvious. The Rhodes '874 publication discloses the features of claim 17, which depends from claim 14.

> Claim 17. The continuous glucose sensor system of claim 14, wherein the resistance domain is configured to have a permeability ratio of at least about 50:1 of oxygen to glucose.

The Rhodes '874 publication teaches implantable glucose sensors employing multi-region membranes which have "enabled function of devices for over one year in vivo." The Rhodes '874 publication, pg. 5, [0061]. Specifically, the Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having the desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6-7, [0082]-[0084]. Specifically,

the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "a permeability ratio of at least about 50:1 of oxygen to glucose."

One of ordinary skill in the art would understand how to modify the resistance domain of the Kerner publication and the Kusano publication, in accordance with the teachings of the Rhodes '874 publication, to meet the claim limitation of "a permeability ratio of at least about 50:1 of oxygen to glucose." The sensor of claim 17 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 17 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication, the Kusano publication, and the Rhodes '874 publication. Claim 17 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

4. Independent Claim 23

Claim 23. A continuous glucose sensor system comprising:
Part of Claim 23

The Kerner publication teaches a continuous glucose sensor system. See, for example, the Kerner publication, Summary, pg. 9, and FIG. 1.

The Kusano publication teaches a continuous glucose sensor system. See, for example, the Kusano publication, Abstract, and Figures 3, 4, and 9. Figures 3, 4, and 9, for example, show continuous sensor readings over an extended period of time.

an implantable body comprising an electrode configured to measure a glucose level in a host;
Part of Claim 23

The Kerner publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See the Kerner publication, Summary, pg. 9, and FIG. 1.

The Kusano publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Kusano publication pgs. 2-3, and Figure 2 (reproduced below).

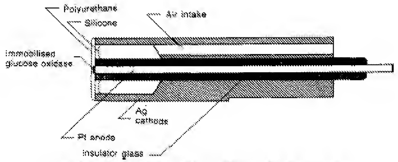


Figure 2. Schematic diagram of the experimental glucose electrode.

The Abstract of the Kusano publication, for example, states "[t]he electrode has been designed to be used with a percutaneous interface for future *in vivo* use."

> a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme configured to catalyze a reaction of glucose and oxygen; and
>
> *Part of Claim 23*

The Kerner publication teaches a membrane disposed over the electrode, wherein the membrane includes a resistance domain configured to limit transport of glucose to the electrode and an enzyme to catalyze a reaction of glucose and oxygen. See the Kerner publication, Summary, pg. 9, and FIG. 1.

The Kusano publication teaches a polyurethane membrane disposed over the electrode. See, for example, Figure 2 (above). The membrane includes a resistance domain configured to limit transport of glucose to the electrode. See, for example, the Kusano publication, pgs. 1-3. Further, the sensor of the Kusano publication includes an enzyme configured to catalyze a reaction of glucose and oxygen. See *Id.*, and Figure 2.

> a sensor electronics unit operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L,
>
> *Part of Claim 23*

The Kerner publication teaches sensor electronics operably connected to the electrode. The electronics unit is configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L. See the Kerner publication, Summary, FIGs. 4 and 5,

and pg. 11. Specifically, the Kerner publication teaches and oxygen concentrations above 0.5 mg/L, which includes concentrations of less than about 0.6 mg/L. *Id.*

The Kusano publication teaches sensor electronics operably connected to the electrode. The sensor electronics measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL, in a fluid with an oxygen concentration of less than about 0.6 mg/L. Specifically, the Kusano publication states, "The glucose electrode with percutaneous interface described in this paper differs from [previously described electrodes] using a novel approach to overcome the lack of oxygen in the interstitial fluid." *Id.* The Kusano publication further states:

> The electrode has a linear response to glucose concentration at an electrode output current ranging from 0 to 20nA ***even when the oxygen concentration of the glucose solution is zero***. The use of polyurethane as a diffusion barrier to glucose limits the electrode output current at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) to 20 nA. Therefore, the electrode can measure glucose concentrations up to 500 mg dl^{-1} (27.8 mmol l^{-1}) ***with no oxygen*** dissolved in the glucose solution.

The Kusano publication, Abstract (emphasis added).

Figure 8 of the Kusano publication (reproduced below) shows a linear current measurement up to 500 mg/dL, even at 0 kPa of Po_2.

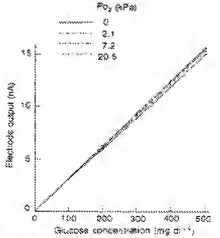


Figure 8. Electrode calibration curves under various Po_2

The concluding remarks of the Kusano publication further state:

> Glucose concentrations of 0 to 500 mg dl^{-1} (27.8 mmol l^{-1}) could be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (21.7 kPa). Since the electrode is capable of operating where the oxygen concentration is low, it is thought to be suitable for implantation in subcutaneous tissue and may prove to be a key development in the realisation of a closed-loop artificial endocrine pancreas.

The Kusano publication, pg. 8.

> wherein the sensor system is configured to have, in operation, a sensitivity of from about 5 pA/mg/dL to about 25 pA/mg/dL.
>
> *Part of Claim 23*

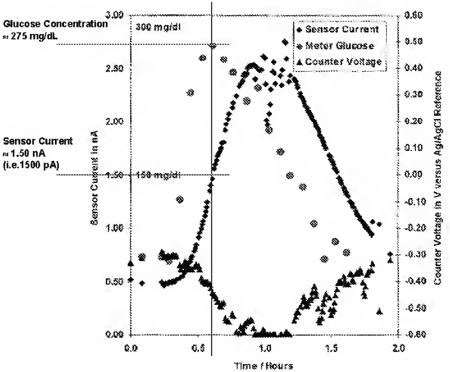
The Kerner publication teaches the sensor system is configured to have, in operation, a sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL, but does not explicitly teach a sensitivity that falls within the claimed range of from about 5 pA/mg/dL to about 25 pA/mg/dL. See the Kerner publication, FIG. 4, and pg. 11.

The Kusano publication states, "In addition, the steady state current at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) should be less than the saturation current which results when the oxygen supplied from the air is limited, which is about 20 nA in this electrode." The Kusano publication, pg. 6. As such, the Kusano publication teaches a sensitivity of less than 40 pA/mg/dL (i.e., 20,000 pA divided by 500 mg dl^{-1}).

The Rhodes '874 publication teaches a sensor system that is configured to have, in operation, a sensitivity of from about 5 pA/mg/dL to about 25 pA/mg/dL. More specifically, the Rhodes '874 publication discloses an implantable glucose sensor that showed no oxygen dependence to oxygen concentrations as low as 0.1 mg/L, and a sensitivity of at least 5.5 pA/mg/dL to increasing glucose concentrations up to 400 mg/dL) of glucose. See the Rhodes '874 publication, FIGs. 3 and 9; and pg. 11, [0131]-[0141].

Figure 3 of the Rhodes '874 publication (reproduced below and annotated for clarity) shows a sensor system configured to have a sensor output of at least 5.5 pA/mg/dL between 0-300 mg/dL. For example, at a glucose concentration of 275 mg/dL, the glucose sensor system of the Rhodes '874 publication has a sensor current of 1.5 nA (i.e., 1500 pA). Therefore, the Rhodes '874 publication discloses a glucose sensor system that has a sensitivity of at least 5.5

pA/mg/dL. As such, the disclosed sensor sensitivity of at least 5 pA/mg/dL in the Rhodes '874 publication falls within the claimed range of about 5 pA/mg/dL to about 25 pA/mg/dL.



One of ordinary skill in the art would understand how to modify the sensitivity of the sensor system of the Kerner publication and the Kusano publication, in accordance with the teachings of the Rhodes '874 publication, to meet the claim limitation of "a sensitivity of from about 5 pA/mg/dL to about 25 pA/mg/dL." The sensor of claim 23 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 23 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication, the Kusano publication, and the Rhodes '874 publication. Claim 23 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

5. Dependent Claim 27

In addition rendering claim 23 obvious, the combination of the Kerner publication, the Kusano publication, and the Rhodes '874 publication discloses the features of claim 27, which depends from claim 23.

> Claim 27. The continuous glucose sensor system of claim 23, wherein the resistance domain comprises a polyurethane.

The Kusano publication teaches the use of polyurethane to limit the penetration of glucose into the enzyme layer. See the Kusano publication, pg. 6.

The sensor of claim 27 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 27 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication, the Kusano publication, and the Rhodes '874 publication. Claim 27 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

6. Dependent Claim 29

In addition rendering claim 23 obvious, the combination of the Kerner publication, the Kusano publication, and the Rhodes '874 publication discloses the features of claim 29, which depends from claim 23.

> Claim 29. The continuous glucose sensor system of claim 23, wherein the oxygen concentration is less than about 0.3 mg/L.

As discussed above, the Kusano publication teaches a sensor configured to measure glucose concentrations "even when the oxygen concentration of the glucose solution is zero." The Kusano publication, Abstract. As such, the Kusano publication meets the claim limitation of the oxygen concentration being less than about 0.3 mg/L. The Kusano publication presents a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.3 mg/L, and thus falls within the scope of claim 29.

One of ordinary skill in the art would understand how to modify the sensor of the Kerner publication, in accordance with the teachings of the Kusano publication to meet the claim limitation of "sensor electronics … configured to measure a current produced by the electrode … in a fluid with an oxygen concentration of less than about 0.3 mg/L." The sensor of claim 29 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 29 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication, the Kusano publication, and the Rhodes '874 publication. Claim 29 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

7. Dependent Claim 30

In addition rendering claim 23 obvious, the combination of the Kerner publication, the Kusano publication, and the Rhodes '874 publication discloses the features of claim 30, which depends from claim 23.

Claim 30. The continuous glucose sensor system of claim 23, wherein the electrode comprises an exposed electroactive working electrode surface with a surface area of from about 0.00002 in^2 to about 0.0079 in^2.

The Kerner publication teaches the electrode includes an exposed electroactive working electrode surface with a surface area between about 0.00002 in^2 and about 0.0079 in^2. See the Kerner publication, pg. 9. The diameter of the working electrode is 0.5 mm (0.0197 in; surface area of about 0.000304 in^2). *Id.*

The Kusano publication teaches an electroactive surface area that falls within the range of 0.00002 in^2 to about 0.0079 in^2. Specifically, the Kusano publication teaches a working electrode with "0.5 µg of albumin-linked glucose oxidase []immobilised at the tip" of a "Pt wire 0.5 mm in diameter." See the Kusano publication, Abstract. The surface area of the electroactive surface is therefore the surface area of the tip of the Pt wire, which is equal to 0.000304 in^2 (Area = $\pi r^2 = (3.14)(0.25mm)^2 = 0.196\ mm^2 = 0.000304\ in^2$). A surface area of 0.000304 in^2 falls within the claimed range of about 0.00002 in^2 to about 0.0079 in^2.

The sensor of claim 30 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 30 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication, the Kusano publication, and the Rhodes '874 publication. Claim 30 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

8. Dependent Claim 31

In addition rendering claim 23 obvious, the combination of the Kerner publication, the Kusano publication, and the Rhodes '874 publication discloses the features of claim 31, which depends from claim 23.

Claim 31. The continuous glucose sensor system of claim 23, wherein the resistance domain is configured to have a permeability ratio of at least about 50:1 of oxygen to glucose.

The Rhodes '874 publication teaches implantable glucose sensors employing multi-region membranes which have "enabled function of devices for over one year in vivo." The Rhodes '874 publication, pg. 5, [0061]. Specifically, the Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having the desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6-7, [0082]-[0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "a permeability ratio of at least about 50:1 of oxygen to glucose."

One of ordinary skill in the art would understand how to modify the resistance domain of the Kerner publication and the Kusano publication, in accordance with the teachings of the Rhodes '874 publication, to meet the claim limitation of "a permeability ratio of at least about 50:1 of oxygen to glucose." The sensor of claim 31 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 31 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication, the Kusano publication, and the Rhodes '874 publication. Claim 31 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

H. Claim 24 is obvious under 35 U.S.C. § 103 in view of the Kerner publication, the Kusano publication, the Rhodes '874 publication, and the Sternberg publication.

As discussed above, claim 23 is rendered obvious by the teachings of the Kerner publication, the Kusano publication, and the Rhodes '874 publication. As outlined below, the combination of the Kerner publication, the Kusano publication, the Rhodes '874 publication, and the Sternberg publication renders claim 24, which depends from claim 23, obvious. For the examiner's convenience, the arguments presented below are summarized in the table provided in **Exhibit M**.

Claim 24. The continuous glucose sensor system of claim 23, wherein the system is configured such that less than about 1μg of enzyme is consumed over 10 days of continuous operation.

The Sternberg publication describes three procedures for preparing electrodes with immobilized glucose oxidase (GOx). See, for example, the Sternberg publication, pgs. 2782-83, and Table I. Procedures "a," "b," and "c" contain 3.0 ± 1.2 μg, 6.4 ± 2.2 μg, and 10 ± 1.4 μg of GOx, respectively. *Id.* More specifically, procedure "a" provides 3.8 ± 1.5 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 3.0 ± 1.2 μg of enzyme; procedure "b" provides 8.0 ± 2.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 6.4 ± 2.2 μg of enzyme; and procedure "c" provides 13 ± 1.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 10 ± 1.4 μg of enzyme.

As discussed on page 2784 of the Sternberg publication, "Figure 5 compares the time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface." The line noted with the "X" markers in Figure 5 (reproduced below) illustrates the consumption of GOx over about 15 days of continuous use.

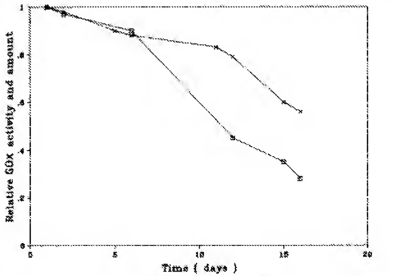


Figure 5. Relative evolution of surface GOx activity (O) and ^{125}I-GOx (X) in a CA-BSA-PBQ-GOx membrane not treated with lysine after coupling.

As shown in Figure 5, the relative consumption of GOx over the first ten days of use is between about 15% and about 20%. Enzyme prepared in accordance with procedure "a" would begin with 3.0 ± 1.2 μg, and result in a consumption of about 0.27-0.84 μg. Enzyme prepared in

accordance with procedure "b" would begin with 6.4 ± 2.2 μg, and result in consumption of about 0.63-1.7 μg. Enzyme prepared in accordance with procedure "c" would begin with 10 ± 1.4 μg, and result in consumption of about 1.3-2.3 μg. As such, the Sternberg publication teaches how to configure the system to consume a range of enzyme mass from about 0.27-2.3 μg over 10 days of continuous operation.

One of skill in the art, in view of the teachings of the Sternberg publication, would thus appreciate how to configure the sensor "such that less than about 1 μg of enzyme is consumed over 10 days of continuous operation." The sensor of claim 24 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 24 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication, the Kusano publication, the Rhodes '874 publication, and the Sternberg publication. Claim 24 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

I. Claims 1, 7, 8, 23, and 31 are anticipated under 35 U.S.C. § 102 by the Rhodes '874 publication.

Claims 1, 7, 8, 23, and 31 are anticipated under 35 U.S.C. § 102(b) by the Rhodes '874 publication. Sections VI.I.1 – VI.I.5 detail how claims 1, 7, 8, 23, and 31 are anticipated under 35 U.S.C. § 102(b) by the Rhodes '874 publication. For the examiner's convenience, the arguments presented below are summarized in the table provided in **Exhibit N**.

1. Independent Claim 1

Claim 1. A continuous glucose sensor system comprising:
Part of Claim 1

The Rhodes '874 publication teaches a continuous glucose sensor system. See the Rhodes '874 publication, Abstract; Figure 1 and page 2, [0012]-[0017].

an implantable body comprising an electrode configured to measure a glucose level in a host;
Part of Claim 1

The Rhodes '874 publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Rhodes '874 publication , Abstract, page 2, [0012]-[0017] and [0020].

> a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme configured to catalyze a reaction of glucose and oxygen; and
>
> *Part of Claim 1*

The Rhodes '874 publication teaches a multi-region membrane disposed over the electrode. See, for example, pages 5, [0062] – page 8, [0108] and Figures 2A-2F. The membrane includes a resistance domain configured to limit transport of glucose to the electrode. See, for example, the Rhodes '874 publication, page 6, [0082] – page 7, [0085]. Further, the sensor of the Rhodes '874 publication includes an enzyme configured to catalyze a reaction of glucose and oxygen. See page 7, [0086]-[0088].

> sensor electronics operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L.
>
> *Part of Claim 1*

The Rhodes '874 publication teaches sensor electronics operably connected to the electrode. The sensor electronics measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL, in a fluid with an oxygen concentration of less than about 0.3 mg/L. The Rhodes '874 publication states that "[a]s a result, the upper limit of linearity of glucose measurement is extended to a much higher value than that which could be achieved without the resistance domain". See pages 6-7, [0083]-0084] Furthermore, the Rhodes '874 publication discloses that testing was conducted up to a glucose concentration of 400 mg/dL and that "sensitivity of the sensor to glucose is given as the slope of sensor output versus glucose concentration". See page 10, [0133] In EXAMPLE 2, on page 10, the Rhodes '874 publication states, "A glucose value was recorded for each device at decreasing oxygen concentrations from ambient to approximately 0.1 mg/L." Pg. 10, [0136]. Because the Rhodes '874 publication was able to record glucose values at oxygen concentrations as low as approximately 0.1 mg/L, the Rhodes '874 publication therefore shows a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.3 mg/L, as called for in claim 1.

Because the Rhodes '874 publication teaches each and every feature of claim 1, the Rhodes '874 publication anticipates claim 1 under 35 U.S.C. § 102(b).

2. Dependent Claim 7

In addition to showing each and every feature of claim 1, the Rhodes '874 publication discloses the features of claim 7, which depends from claim 1. Because the Rhodes '874 publication teaches each and every feature of claim 7, the Rhodes '874 publication anticipates claim 7 under 35 U.S.C. § 102(b).

Claim 7. The continuous glucose sensor system of claim 1, wherein the resistance domain is configured to have a permeability ratio of at least about 50:1 of oxygen to glucose.

The Rhodes '874 publication teaches implantable glucose sensors employing multi-region membranes which have "enabled function of devices for over one year in vivo." The Rhodes '874 publication, pg. 5, [0061]. Specifically, the Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having the desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6-7, [0082]-[0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "a permeability ratio of at least about 50:1 of oxygen to glucose."

3. Dependent Claim 8

In addition to showing each and every feature of claim 7, the Rhodes '874 publication discloses the features of claim 8, which depends from claim 7. Because the Rhodes '874 publication teaches each and every feature of claim 8, the Rhodes '874 publication anticipates claim 8 under 35 U.S.C. § 102(b).

Claim 8. The continuous glucose sensor system of claim 7, wherein the resistance domain is configured to have a permeability ratio of at least about 200:1 of oxygen to glucose.

The Rhodes '874 publication teaches implantable glucose sensors employing multi-region membranes which have "enabled function of devices for over one year in vivo." The Rhodes '874 publication, pg. 5, [0061]. Specifically, the Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having the desired ratios of

diffusion. See, for example, the Rhodes '874 publication, pgs. 6-7, [0082]-[0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "a permeability ratio of at least about 200:1 of oxygen to glucose."

4. Independent Claim 23

Claim 23. A continuous glucose sensor system comprising: *Part of Claim 23*

The Rhodes '874 publication teaches a continuous glucose sensor system. See the Rhodes '874 publication, Abstract; Figure 1 and page 2, [0012]-[0017].

an implantable body comprising an electrode configured to measure a glucose level in a host; *Part of Claim 23*

The Rhodes '874 publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Rhodes '874 publication , Abstract, page 2, [0012]-[0017] and [0020].

a membrane disposed over the electrode, wherein the membrane comprises a resistance domain configured to limit transport of glucose to the electrode and an enzyme configured to catalyze a reaction of glucose and oxygen; and *Part of Claim 23*

The Rhodes '874 publication teaches a multi-region membrane disposed over the electrode. See, for example, pages 5, [0062] – page 8, [0108] and Figures 2A-2F. The membrane includes a resistance domain configured to limit transport of glucose to the electrode. See, for example, the Rhodes '874 publication, page 6, [0082] – page 7, [0085]. Further, the sensor of the Rhodes '874 publication includes an enzyme configured to catalyze a reaction of glucose and oxygen. See page 7, [0086]-[0088].

> a sensor electronics unit operably connected to the electrode and configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L,
>
> *Part of Claim 23*

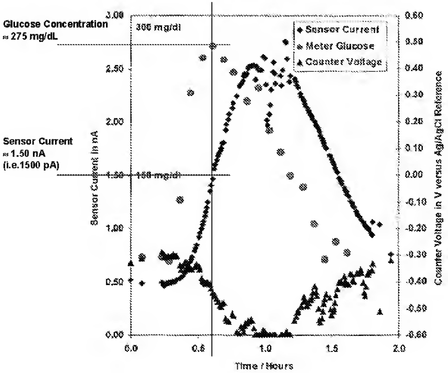
The Rhodes '874 publication teaches sensor electronics operably connected to the electrode. The sensor electronics measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL, in a fluid with an oxygen concentration of less than about 0.6 mg/L. The Rhodes '874 publication states that "[a]s a result, the upper limit of linearity of glucose measurement is extended to a much higher value than that which could be achieved without the resistance domain". See pages 6-7, [0083]-0084] Furthermore, the Rhodes '874 publication discloses that testing was conducted up to a glucose concentration of 400 mg/dL and that "sensitivity of the sensor to glucose is given as the slope of sensor output versus glucose concentration". See page 10, [0133] In EXAMPLE 2, on page 10, the Rhodes '874 publication states, "A glucose value was recorded for each device at decreasing oxygen concentrations from ambient to approximately 0.1 mg/L." Pg. 10, [0136]. Because the Rhodes '874 publication was able to record glucose values at oxygen concentrations as low as approximately 0.1 mg/L, the Rhodes '874 publication therefore shows a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.6 mg/L, as called for in claim 23.

> wherein the sensor system is configured to have, in operation, a sensitivity of from about 5 pA/mg/dL to about 25 pA/mg/dL.
>
> *Part of Claim 23*

The Rhodes '874 publication teaches a sensor system that is configured to have, in operation, a sensitivity of from about 5 pA/mg/dL to about 25 pA/mg/dL. More specifically, the Rhodes '874 publication discloses an implantable glucose sensor that showed no oxygen dependence to oxygen concentrations as low as 0.1 mg/L, and a sensitivity of at least 5.5 pA/mg/dL to increasing glucose concentrations up to 400 mg/dL) of glucose. See the Rhodes '874 publication, FIGs. 3 and 9; and pg. 11, [0131]-[0141].

Figure 3 of the Rhodes '874 publication (reproduced below and annotated for clarity) shows a sensor system configured to have a sensor output of at least 5.5 pA/mg/dL between 0-300 mg/dL. For example, at a glucose concentration of 275 mg/dL, the glucose sensor system of

the Rhodes '874 publication has a sensor current of 1.5 nA (i.e., 1500 pA). Therefore, the Rhodes '874 publication discloses a glucose sensor system that has a sensitivity of at least 5.5 pA/mg/dL. As such, the disclosed sensor sensitivity of at least 5 pA/mg/dL in the Rhodes '874 publication falls within the claimed range of about 5 pA/mg/dL to about 25 pA/mg/dL.



Because the Rhodes '874 publication teaches each and every feature of claim 1, the Rhodes '874 publication anticipates claim 1 under 35 U.S.C. § 102(b).

5. Dependent Claim 31

In addition to showing each and every feature of claim 23, the Rhodes '874 publication discloses the features of claim 31, which depends from claim 23. Because the Rhodes '874 publication teaches each and every feature of claim 31, the Rhodes '874 publication anticipates claim 31 under 35 U.S.C. § 102(b).

Claim 31. The continuous glucose sensor system of claim 23, wherein the resistance domain is configured to have a permeability ratio of at least about 50:1 of oxygen to glucose.

The Rhodes '874 publication teaches implantable glucose sensors employing multi-region membranes which have "enabled function of devices for over one year in vivo." The Rhodes '874 publication, pg. 5, [0061]. Specifically, the Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having the desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6-7, [0082]-[0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "a permeability ratio of at least about 50:1 of oxygen to glucose."

VII. CERTIFICATION OF SERVICE (37 C.F.R. § 1.510(b)(5))

The United States Patent and Trademark Office records indicate that the Shults '352 patent is presently assigned to DexCom, Inc. (see Assignment recorded at Reel/Frame: 020893/0207). The undersigned certifies that the request for *ex parte* reexamination has been served by Federal Express, deposited on February 1, 2011, on the patent owner at the correspondence address provided in the USPTO PAIR system:

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
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IRVINE CA 92614

VIII. STATEMENT OF AUTHORITY TO ACT ON BEHALF OF THE REAL PARTY IN INTEREST PURSUANT TO 37 C.F.R. § 1.34

The undersigned states that he is acting on behalf of the Requestor, Abbott Diabetes Care Inc., in a representative capacity pursuant to 37 C.F.R. § 1.34.

IX. CONCLUSION

For the reasons given above, reexamination of claims 1-9, 12, 14-18, 21, 23, 24, 27, and 29-31 of U.S. Patent No. 7,771,352 is respectfully requested.

The USPTO is directed and authorized to charge all Requestor's required fees associated with the Request to Deposit Account No. 50-0815, order number ADCI-GEN51, as well as credit any overpayments to said Deposit Account.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: February 1, 2011

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XI. EXHIBIT LIST

Exhibit No.	Description
Exhibit A	U.S. Patent No. 7,771,352 to Shults *et al.*, issued on August 10, 2010.
Exhibit B	Kerner, *et al.*, A Potentially Implantable Enzyme Electrode for Amperometric Measurement of Glucose, *Horm Metab Res Suppl.*, 20:8-13 (1989).
Exhibit C	Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissolved oxygen, *Clin. Phys. Physiol. Meas.*, vol. 10, 1:1-9 (1989).
Exhibit D	Sternberg, *et al.*, Covalent Enzyme Coupling on Cellulose Acetate Membranes for Glucose Sensor Development, *Anal. Chem.*, 60: 2781-2786 (1988)
Exhibit E	U.S. Patent Publication No. 2003/0032874 to Rhodes *et al.*, published on February 13, 2003.
Exhibit F	Table illustrating that each element of claims 1, 3-6, 9, and 12 is provided by the Kusano publication.
Exhibit G	Table illustrating that each element of claims 2, 14-16, 18 and 21 is provided by the Kusano publication and the Sternberg publication.
Exhibit H	Table illustrating that each element of claims 7, 8, 17, 23, 27 and 29-31 is provided by the Kusano publication and the Rhodes '874 publication.
Exhibit I	Table illustrating that each element of claim 24 is provided by the Kusano publication, the Rhodes '874 publication and the Sternberg Publication.
Exhibit J	Table illustrating that each element of claims 1, 3-6, 9, and 12 is provided by the Kerner Publication and the Kusano publication.
Exhibit K	Table illustrating that each element of claims 2, 14-16, 18 and 21 is provided by the Kerner Publication, the Kusano Publication and the Sternberg Publication.
Exhibit L	Table illustrating that each element of claims 7, 8, 17, 23, 27 and 29-31 is provided by the Kerner publication, the Kusano publication and the Rhodes '874 publication.
Exhibit M	Table illustrating that each element of claim 24 is provided by the Kerner publication, the Kusano publication, the Rhodes '874 publication and the Sternberg Publication.
Exhibit N	Table illustrating that each element of claims 1, 7, 8, 23 and 31 is provided by the Rhodes '874 publication.